

CLINICAL DECISIONS

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Sepsis Guidelines

This interactive feature addresses the approach to a clinical issue. A case vignette is followed by specific options, neither of which can be considered either correct or incorrect. In short essays, experts in the field then argue for each of the options. Readers can participate in forming community opinion by choosing one of the options and, if they like, providing their reasons.

CASE VIGNETTE

A Hospital Considering a 1-Hour Bundle for Management of Sepsis

Angela X. Chen, M.B., B.S., M.P.H.

You are the chair of the emergency department at a community hospital. There is a small critical care unit on site, but patients requiring more comprehensive care are transferred to another hospital.

You have been discussing sepsis management with colleagues because of the recent release of updated sepsis guidelines. The guidelines recommend that for all patients presenting with sepsis, the condition should be managed with a set of interventions, known as a “bundle,” within 1 hour after presentation (defined as the “time of triage in the emergency department or, if referred from another care location, from the earliest chart annotation consistent with all elements of sepsis [formerly severe sepsis] or septic shock ascertained through chart review”¹). The bundle consists of measuring lactate level, obtaining blood cultures before administering antibiotics, administering broad-spectrum antibiotics, administering 30 ml of crystalloid per kilogram of body weight if the patient has hypotension or a lactate level higher than 4 mmol per liter, and administering vasopressors if the patient remains hypotensive despite fluid resuscitation.

A bundle of interventions is already in place in your hospital, but the current goal is to complete the bundle within 3 hours. You are aware that evaluation of a New York State–mandated

time-to-treatment goal for the emergency care of patients with sepsis showed that faster completion of the 3-hour bundle was associated with lower in-hospital mortality². Since the release of the updated guidelines, members of the critical care department have been advocating for implementing the guidelines’ recommendations and completing the bundle within 1 hour, to further improve patient outcomes. However, emergency department staff have expressed concerns that tightening the 3-hour bundle to 1 hour would draw resources away from other time-sensitive emergencies and might adversely affect emergency department performance measures.

The hospital administrator approaches you to discuss the appropriateness of adopting a 1-hour goal for the sepsis bundle. In particular, the hospital leadership is asking how implementation could affect patient outcomes and quality of care, as well as emergency department and hospital system performance measures.

OPTIONS

Which one of the following approaches would you recommend for this hospital? Base your choice on the published literature, your own experience, published guidelines, and other information sources.

1. Adopt a 1-hour goal for the sepsis bundle.
2. Maintain the 3-hour goal for the sepsis bundle.

To aid in your decision making, each of these approaches is defended in a short essay by an expert in the field. Given your knowledge of the issue and the points made by the experts, which approach would you choose?

OPTION 1

Adopt a 1-Hour Goal for the Sepsis Bundle

Steven Q. Simpson, M.D.

Sepsis and septic shock are medical emergencies, and treatment and resuscitation should be-

gin immediately.³ Our first priority as physicians and health care providers is to protect our patients from harm, and there is little question that bundled sepsis care helps us do so. The weight of evidence clearly indicates that earlier sepsis treatment results in a greater chance of survival, and no studies suggest that slower

treatment is better.³ As noted in the vignette, the experience in New York², where sepsis bundles are mandated, provides good evidence that the sooner the sepsis bundle is completed, the more likely patients are to survive. Data from northern California showed that earlier administration of antibiotics and fluid boluses of 30 ml per kilogram reduced mortality.^{4,5} A study conducted in Minnesota showed that among patients who were treated according to the 3-hour bundle, survival to discharge from the hospital was greater among those who were treated earlier, and each element of the bundle contributed.⁶ Given these outcomes across the United States, the logical step is to hold ourselves to standards that encourage the swiftest possible intervention, such as a 1-hour goal for completion of our initial treatment bundle.

Arguments against a 1-hour bundle typically represent one or more of the following positions: a disbelief that sepsis actually is an emergency, a belief that a single dose of broad-spectrum antibiotics represents a greater risk of harm to a noninfected patient than it does a potential benefit to a patient with infection-induced life-threatening organ dysfunction, and a belief that a bolus of 30 ml per kilogram is too much for some patients. Disbelief that sepsis is an emergency is the most problematic of these ideas and is, in fact, the root cause of the latter two. Such disbelief most likely stems from the fact that sepsis, in general, does not evolve as rapidly as sudden cardiac death, stroke, or traumatic hemorrhage. Progression from sepsis to septic shock increases by 8.0% per hour from presentation until administration of antimicrobial agents.⁷ However, shock associated with early treatment delays takes time to develop — a median of 26.5 hours — and therefore the progression to shock is not witnessed by emergency department personnel. Skepticism about the emergency nature of sepsis results from the fact that neither emergency department personnel nor critical care physicians see the full clinical picture from beginning to end.

A 1-hour goal for the bundle is aspirational and provides a framework for continuing to improve our diagnostic and therapeutic endeavors; diagnosing sepsis can indeed be challenging, but setting lofty goals encourages us to do so as quickly as possible. A commitment to continu-

ally improve our care of patients with sepsis, indeed our care of all patients, should be our guide — not fear of nonexistent penalties or less-than-stellar performance measures. The sepsis score cards distributed in the hospital where I work have always included a 1-hour internal goal for completion of the bundle. In the majority of cases we do not succeed, but we aspire. We continue to address our systems of care, and we do not believe that emergency care is a zero-sum game. All patients with time-sensitive illness must be given the best possible care in the most expedient way — patients with sepsis included.

Disclosure forms provided by the author are available with the full text of this article at NEJM.org.

From the Division of Pulmonary and Critical Care Medicine, University of Kansas, Kansas City.

OPTION 2

Maintain the 3-Hour Goal for the Sepsis Bundle

Daniel J. Pallin, M.D., M.P.H.

The 1-hour bundle has been broadly recognized as a bad idea, and we should not use it to guide practice. The American College of Emergency Physicians and the Society of Critical Care Medicine “recommend that hospitals do not implement the Hour-1 bundle in its present form.”⁸ This is not an isolated controversy, since the 1-hour bundle is a product of the Surviving Sepsis Campaign, which is a questionable project at best. In 2006, the Infectious Diseases Society of America did not endorse the 3-hour bundle owing to concerns regarding conflict of interest and faulty methodology.⁹

Nobody has shown definitively that the 1-hour bundle would help patients, and many are concerned that it could be useless or even harmful.^{10,11} There is little evidence to support the bundle as a whole, since it has not been tested in a clinical setting. Even advocates of the bundle acknowledge that the evidence supporting its individual elements ranges in quality from low to moderate.¹

“Time zero” for the 1-hour bundle is defined as “the time of triage in the emergency department or, if referred from another care location, from the earliest chart annotation consistent with all elements of sepsis (formerly severe sep-

sis) or septic shock ascertained through chart review.” The targeted disease is described as “sepsis (formerly severe sepsis).” This illustrates fundamental problems with construct validity in the term “sepsis”; the definition has been in flux for decades.¹² Which patients should we target? No real specification is provided on this crucial question.

The 1-hour bundle could hurt some patients with sepsis. Aggressive fluid resuscitation intended to comply with a regulatory mandate will hinder patient-centered care, and some patients with sepsis (such as those with congestive heart failure or end-stage renal disease) will be harmed by overly aggressive hydration. Furthermore, the 1-hour bundle will divert attention away from emergencies that are amenable to interventions for which time-sensitivity has been proved by high-quality evidence (e.g., myocardial infarction and stroke) or from emergencies that clearly require urgent action (e.g., exsanguination and asphyxiation).

Only a minority of the patients touched by the 1-hour bundle will ever receive a confirmed diagnosis of sepsis and come under the care of a member of the critical care department. Multiple performance metrics (e.g., wait times) would suffer for other patients. Meanwhile, we would often be administering broad-spectrum antibiotics to uninfected patients, wasting our nurses' time, and consuming blood culture bottles and other supplies.

The explicit intention to use a retrospective lens to critique emergency care (“earliest chart annotation consistent with...”) is inimical to the realities of emergency care. It is all too easy to cast aspersions on the emergency care of patients with a particular disease if you ignore the fact that, at the time of the patient's presentation, the disease may be indistinguishable from a multitude of other conditions.

We in the Department of Emergency Medicine devote our careers to achieving the best possible outcomes for all our patients. We follow applicable research and guidelines, and we decide carefully how they should be applied to the care of all patients, a small number of whom may have any particular diagnosis. The focus on the numerator of sepsis by critical care specialists who do not understand the vast denominator of conditions that would trigger the bundle is an

unfortunate continuing trend. It is reminiscent of the unsuccessful attempt by the Centers for Medicare and Medicaid Services to mandate blood cultures for 100% of patients admitted with community-acquired pneumonia.

The flag of evidence-based medicine was raised after a hard-fought battle, and regression to “eminence-based” medicine is a constant danger. A quotation from an 1815 essay by John Allan, titled “Observations on the Necessity and Utility of Blood-letting in Continued Fever,” reminds us how far we've come: “The benefit resulting to the science of medicine from the theories invented by eminent men, have never been altogether free from some inconvenience.”¹³

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From Brigham and Women's Hospital and Harvard Medical School — both in Boston.

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