POSITION STAMENTE

Latin American Sepsis Institute

NEW 1-HOUR BUNDLE: PROS AND CONS FROM THE PERSPECTIVE OF THE LATIN AMERICAN INSTITUTE OF SEPSIS

Context

In April 2018, the Surviving Sepsis Campaign (SSC) published an update to the sepsis treatment bundles in Intensive Care Medicine and later on the SSC website. This publication effectively eliminated the 3-hour and 6-hour bundles, creating a new 1-hour bundle. The components of this bundle reproduced those of the 3-hour bundle, namely lactate sampling, blood culture sampling, antimicrobial administration, and fluid resuscitation for specific patients. In addition, the 1-hour bundle included the initiation of vasopressors, previously part of the 6-hour bundle. The other components of the 6-hour bundle, such as the repeat lactate collection for patients with initial hyperlactatemia, are now expected to be completed within 2 to 4 hours. Although mentioned in the new 1-hour bundle, these elements are no longer formally part of the bundle. The reevaluation of the fluid status and perfusion in shock patients was removed. The authors made it clear that hemodynamic resuscitation should begin within the first hour, but not necessarily all measures must be completed in that timeframe.

Certain aspects of this update are quite positive. However, some points are challenging to implement in practice, and others are, in our view, negative. To fully understand the changes, it's crucial to know a few details about the SSC's organization. The Campaign, an initiative of the European and American intensive care societies (European Society of Intensive Care Medicine - ESICM and Society of Critical Care Medicine - SCCM), is composed of two interlinked but distinct groups. The group responsible for generating recommendations include several participations from various international societies, including ILAS since the 2008 version. However, the group responsible for creating the bundles focuses on the American healthcare system, which may not necessarily align with healthcare systems in other countries.

The first positive aspect of the new bundle is speed. It introduces the necessary sense of urgency when treating a sepsis patient. Even in countries with limited resources, where adherence to the new bundle might be challenging, the message is clear: Sepsis is an emergency, and it should be treated as such. The interventions must be initiated quickly, once a patient is identified with suspected sepsis.

Another positive aspect is that it finally aligns with the SSC guidelines. The new bundle complies with previously outlined guidelines, as it was already clearly recommended to aim for one hour for antimicrobial administration. Since the recommendation was to collect cultures before administration, the expectation of collecting them within this timeframe was implicit. For this reason, for example, in quality programs guided by ILAS, adherence was only granted when antimicrobial administration occurred within the first hour.

However, both culture collection and antimicrobial administration were part of the 3-hour bundle. As a result, the Centers for Medicare and Medicaid Services (CMS) in the United States, through its Sep-1 program used to assess treatment adequacy and hospital reimbursement, considered that compliance was met even if these measures were taken within 3 hours. In other words, within the American quality program, changing the bundles introduces new challenges. But for Brazilian hospitals in the ILAS network, the challenge has been present for some time.

However, there are significant sources of confusion and difficulties in implementation. The patient is not always hypotensive at the onset of sepsis. In these cases, it's necessary to create two zero moments. The initial zero moment is when the sepsis protocol is opened due to a suspected sepsis, for patients without hypotension. If hypotension occurs later, a new zero moment is created at its onset, marking when fluid resuscitation should begin. From a practical standpoint, the exact initiation of vasopressors within one hour is challenging to define, as it depends heavily on the patient's initial response to fluid resuscitation.

There are also some clearly negative points. The elimination of the 6-hour bundle could lead to a potential loss of patient follow-up. Difficulties in measuring adherence to this indicator in the United States might have influenced the decision to eliminate it, given that CMS adopted a stringent method of measurement. The repeat lactate collection for patients with initial hyperlactatemia and the reevaluation of fluid status and perfusion in shock patients were part of this bundle. This reevaluation is crucial, as it guides further decisions. From a quality improvement perspective, maintaining the multidisciplinary team's focus on critical patients, especially those with shock or initial hyperlactatemia, is an advantage. One of the previous criticisms of the bundles was their excessive focus on the early hours, with a subsequent loss of patient care continuity. By focusing solely on the first hour of care, there's a risk of follow-up loss. The repeat lactate measurement remains a follow-up item to be completed within 2 to 4 hours after the initial collection. However, disconnecting it from a bundle could lead to its devaluation.

Given these points, ILAS, in its quality improvement program, chose to adopt the new 1-hour bundle, with caveats.

- **Antimicrobial administration**: No changes were made, as we already followed the one-hour target.

- **Blood culture sampling**: In practice, there were no changes, as it should be done before antimicrobial administration. However, we will now strictly adhere to the one-hour limit instead of three hours.

- **Lactate sampling:** Although adherence was formally given for samples collected within three hours, the recommendation was to collect it within the first hour. Now, we will strictly adhere to the one-hour limit.

- **Fluid administration in pertinent situations**: We will use the onset of hypotension or the time of lactate sampling with hyperlactatemia as the zero moment for starting fluid resuscitation.

- **Vasopressor use**: We do not believe it is feasible to define the need to initiate within one hour, as the indication will depend on each patient's response to the initial fluid resuscitation.

- **Second lactate sampling**: We understand that it is essential to maintain this indicator, which now has a time limit of 4 hours, as suggested by the new bundle.

- **Reevaluation of fluid status and perfusion in shock patients**: We consider it essential to maintain this indicator to keep the team's focus on the patient. Thus, this will be maintained, with a six-hour limit for completion.

We are available for any further clarifications.

São Paulo, May 22, 2018

Board of Directors, Latin American Sepsis Institute