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### Do Care Bundles Help in Implementing Sepsis Guidelines

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A new set of guidelines has been published recently in Critical Care Medicine and Intensive Care Medicine (Dellinger et al. 2008a; Dellinger et al. 2008b), representing the consensus of a group of renowned sepsis experts, and supported by a large number of national and international critical care societies. All recommendations were graded according to a grading system based on both their strengths and levels of published evidence, after an extensive review of the literature. The result of this endeavor is a dense 43 page-text, with 46 different recommendations, and 341 references (Dellinger et al. 2008b). Although many recommendations were graded as "strong", few of them had high levels of published evidence, particularly in key elements of sepsis therapy.

#### Concerns

Physicians are now faced with the crucial decision of whether they should follow these recommendations or disregard them. Their decision depends both on their overall confidence in the guidelines as they are laid out, as well as their individual belief that a given therapy is good for their patients or not. It seems obvious that guidelines are made to guide in a general sense, and may not be applicable to all patients, particularly in the case of sepsis being such a heterogeneous syndrome. A blind application of guidelines as strict treatment rules is most probably even dangerous. Other factors need to be taken into consideration, such as co-morbidities, prognostic aspects, particular septic patients subpopulations, availability for some of these therapies, etc. It is impossible that guidelines may take into account all these different situations, and modulation of the therapeutic approach for a given patient is generally the rule. Another issue that invariably arises when it comes to guidelines is the possible conflicts of interest of panel members linked to their relation with the industry as well as their personal scientific interests, which may impact on grading strength and levels of evidence for a given recommendation. These conflicts need to be clearly stated in the guidelines document, which was the case for the 2008 sepsis guidelines, at least for relations with the industry (Dellinger et al. 2008a; Dellinger et al. 2008b). The need for a consensus among a large panel of experts is also likely to avoid biased decisions derived from significant conflict of interests of a small number of experts.

#### Guidelines

Physicians may like or dislike guidelines or protocol-oriented care, but evidence exists in the literature that when protocols are implemented in an ICU, they are generally associated with improved outcome. This has for example been elegantly shown for ventilator weaning protocols. This may be due to different factors, including the indisputable value of measuring performance, and that the development of a protocol requires us as physicians to rethink our approach, write it down, and make the effort to educate caregivers during the implementation process. Protocols have also, in our specialty, the great advantage of obliging us to deal with essential issues such as timing and logistics. A treatment is good not only because of its nature, but also because it is given to the right patient, at the right dose, and at the right time. Protocols may thus be considered as a minimal or basic standard of care on which modulation for a given patient or situation is possible.

#### Use of Protocols in Management of Sepsis

In the case of sepsis treatment, physicians still face the problem of generating and implementing a protocol based on > 40 different therapeutic measures. Implementing them all at once or alternatively one by one in a protocol seems both insurmountable and illogical. A group of sepsis experts, members of the Surviving Sepsis Campaign, extracted 10 therapeutic measures from the 2004 sepsis guidelines (Dellinger et al. 2004) that they felt were most important for the treatment of septic patients. They proposed to implement them all at once - the sepsis bundles - with the theoretical advantage of the addition of benefits of the 10 measures ([www.ih.org](http://www.ih.org)). This protocol was divided into two parts. This first part (resuscitation bundle, to be achieved within 6 hours after recognition of severe sepsis or septic shock) included items such as early recognition of the severity (lactate measurement), microbiological cultures before an early administration of antibiotic therapy, and early-goal directed fluid and vasopressor resuscitation. The second part (management bundle, to be achieved within 24 hr after recognition of severe sepsis or septic shock)

included items such as glucose control, 'low stretch' mechanical ventilation, and the recognition and treatment of patients who may benefit from hydrocortisone and activated protein C therapy.

### **Implementing Guidelines**

Implementing sepsis bundles is a challenge and takes resources. It is for example important to have a good knowledge of where in the institution the initial care of septic patients is performed, to target the right population of caregivers to instruct, and also (perhaps) to adapt the protocol to the local situation. It is also crucial to decide what educational strategy will be needed to have a chance to achieve the pre-defined goals. We also feel that it is important to make the effort of measuring performance, i.e. adherence to bundles and mortality, to be able to control for the efficacy of implementing the bundles, and to motivate the troops. We have recently implemented the sepsis bundles in our institution, and opted for a multimodal approach. We had previously identified that the initial care of septic patients was mostly performed in the emergency room. Educational tools included the publication of pocket guidelines and posters, dedicated courses for nurses, interns and fellows, frequent feedback to caregivers on their performance (% adherence to items of the bundles and % mortality), patrolling of a dedicated research nurse in the emergency department (ED) and in the ICU with one-on-one discussions with doctors in case of suboptimal care. Before implementing the sepsis bundles protocol, we had measured outcomes, which served as a baseline for further measurements during the implementation and follow-up periods. We have significantly ameliorated the compliance of caregivers for all the elements of the sepsis bundles. Preliminary analysis of the data on 200 patients shows that 71% of patients received adequate care according to the resuscitation bundle after the implementation period as compared with 48% before. Door-to-perfusion of antibiotics time was cut in half. Mortality in patients resuscitated according to the sepsis bundle (all items) was 12%, compared with a mortality of 27% in patients in whom one or more items were missing ( $p = 0.02$ ). These results indicate that the implementation of sepsis bundles can modify clinical practice, positively and significantly impact survival rates (Gao et al. 2005).

### **Future of Sepsis Management**

A reappraisal of the elements composing the sepsis bundles may be necessary in the future, given new publications on sepsis management. For example, recent papers on hydrocortisone therapy and glucose control cast some doubts on their usefulness in the management of patients with severe sepsis and septic shock (Sprung et al. 2008; Brunkhorst et al. 2008). In the most recent sepsis guidelines, both therapies received weak recommendations. For glucocorticoids substitution, it becomes apparent that not all septic shock patients may require this treatment. Doubts still exist whether the most severe patients may require substitution, and many clinicians still give steroids despite the publication of the CORTICUS trial (Sprung et al. 2008). Tight glucose control seemed to cause harmful effects in a recent multicentre German trial (Brunkhorst et al. 2008). However sepsis guidelines do not suggest tight control, but to prevent 'excessive' hyperglycemia with insulin treatment. The administration of activated protein C has also been a matter of intense debate. A multicentre placebocontrolled trial has been initiated in patients with septic shock, which will hopefully settle the issue with this treatment.

### **Conclusion**

The implementation of guidelines using a bundle of measures seems to be a valuable approach, and large trials are now needed to confirm or infirm this. If anything, it forces caregivers to rethink, revise and perfect their treatment protocols, perform education, dialogue with other units and departments, and measure outcomes. Such a program is likely to favor 'state of the art' care, and positively impact on the outcome of patients with severe sepsis and septic shock.

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