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The severe sepsis bundles as processes of care: A meta-analysis

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Summary
Objective: The use of the sepsis bundles in patients with severe sepsis and septic shock has been controversial in the last decade. Clinical studies have reported beneficial, as well as negative results. We conducted a meta-analysis to assess the clinical evidence and to evaluate survival effects.
Data source: Database searches (2004—current) of Medline, CINAHL, Pubmed, Cochrane, Scopus and Google scholar databases which covered full publications, abstracts from conferences and digital thesis were performed using the search terms sepsis, septic shock and/or bundles, processes of care, guidelines, early goal directed therapy, resuscitation.
Results: From 253 identified studies, 21 sepsis bundle original studies were selected and included 23,438 patients. The Resuscitation 6 hour Bundle pooled analysis (1819 patients) achieved the greatest survival benefit (odds ratio (OR) 2.124, 95% CI 1.701—2.651, $p < 0.000$) with the Management 24 hour Bundle pooled analysis the lowest survival benefit (16,521 patients) (OR 1.646, 95% CI 1.036—2.614, $p < 0.035$). Both bundles together (Complete Bundle) achieved a combined survival benefit (OR 1.744, 95% CI 1.421—2.141, $p < 0.000$). ScvO2 and blood glucose components were analysed individually to assess their contribution to survival.

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Conclusion: The Resuscitation 6 hour bundle in the context of the patient population at hand is unlikely to do harm and is yet to be established in primary research in Australia. The Management 24 hour Bundle could not establish a strong enough survival benefit above current routine practice. The sepsis guidelines and bundles have demanded more credible process measurements and debate to induce positive changes in the intervention and treatment care of patients with severe sepsis.

In this last decade ''care bundles'' have transformed clinical practice resulting in greater synergy and teamwork within the ''best practice'' endeavour. A bundle is a selected set of interventions or processes of care distilled from evidence-based practice components that when implemented as a group presents a more robust picture of the quality of care provided, benchmarks performance and improves patient outcomes.[1] Reports that several practices instituted together could reduce the prevalence of catheter-related infection or mortality in mechanically ventilated patients support this approach.[2,3] Interestingly, care bundles have also been observed to work more effectively together as a one process rather than simply a sum of its components. In addition, this phenomenon remains to be fully investigated but one hypothesis suggests that care bundle application and compliance result in changes to the clinical team behaviour and performance rather than just the survival attributes of each bundle component.[4] There is gathering evidence that this concept of care bundles is gaining endorsement. In Australia, the Australian Commission on Safety and Quality in Health Care has endorsed the use of 'bundles' and surveillance for the prevention of health care acquired infections.[5] In the United States, recent comprehensive prevention programs that 'bundle' a group of three to five evidence-based Health Care Associated Infection (HAI) strategies have significantly reduced ICU-acquired infections.[6] Likewise, critical care nurses are familiar with the ''FAST HUG'' acronym[7] (Feeding, Analgesia, Sedation, Thromboembolic prophylaxis, Head-of-bed elevation, stress Ulcer prevention, and Glucose control), which has become part of critical care unit culture and performance indicators. FAST HUG is a concept, not a bundle, but illustrates how evidential protocols combined together can assist with quality care delivery.

In the last decade the Surviving Sepsis Campaign (SSC) has produced the well endorsed guidelines for the care of patients' meeting the criteria for severe sepsis first in 2004[8] and then updated in 2008.[9] From these guidelines the ''Severe Sepsis Bundles'' have been formulated consisting of Resuscitation 6 hour Bundle and a Management 24 hour Bundle as described in Table 1. Initially the SSC was promoted with pharmaceutical companies' funding and promotion, although generally welcomed led to strong criticism by various groups, which was equally robustly rebutted.[10–13] Additionally, the reliance on predominantly single studies with remarkable survival outcomes such as Rivers et al.[14] for early goal directed therapy (EGDT) the main component of the Resuscitation Bundle, has led to a decade of debate leaving the clinician at the beside unsure of the effectiveness of the evidence.[15]

In Australia where the mortality rate for severe sepsis is one of the lowest in the world, scepticism and doubt regarding the utility of the sepsis bundles are ubiquitous.[16] On the other hand, low Australian mortality rates may be associated with processes of care such as shorter waiting times in emergency departments[17] and ease of access to affordable medical care including critical care services compared to other countries.[18] Irrespective of these issues, the Australian and New Zealand Intensive Care Society (ANZICS) could not support the 2008 sepsis guidelines and is reported in an editorial by Hicks and colleagues:

''ANZICS has therefore reluctantly concluded that it would not be appropriate to sponsor the entire package of the 2008 Guidelines, because some components did not reflect current practice in Australia and New Zealand and some have not been proven superior to current practice bi-nationally.''[19(p149)]

This statement has clinical practice consequences and questions remain regarding best evidence based care for patients with severe sepsis, especially in Australia. The critical care fraternity are still to be convinced regarding the benefit of the sepsis bundles, especially when the mortality rate is lower than the intervention group of Rivers and colleagues.[14,20]

In the randomized controlled trial performed by Rivers et al., the resuscitation protocol was