Robert G. Masterton

Sepsis care bundles and clinicians

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R. G. Masterton () Ayrshire & Arran NHS Board, The Ayr Hospital, Dalmellington Road, Ayr KA6 6DX, UK e-mail: robert.masterton@aaaht.scot.nhs.uk Tel.: +44-1292-614511 Fax: +44-1292-288952

Care bundles as part of sepsis management are fast developing a seductive allure for clinicians. In this journal a care bundle introduction into an intensive care unit is described as a way of controlling ventilator-associated pneumonia [1]. Although this was associated with clinically and statistically significant patient benefits, a key feature was that the care bundle was merely a part of an overall programme including surveillance, feedback reporting and staff education. The very high level of current interest in sepsis care bundles makes it appropriate to understand their key components, not just their successes but also their limitations.

Care bundle approaches have been practised across a variety of clinical indications, particularly cardiology, for over 20 years, but only in this decade has their application in sepsis management evolved. An early contribution was the introduction of the concept of structured assessment, severity recognition and early goal-directed therapy [2]. A statistically significant reduction occurred in both hospital (30.5 vs. 46.5%) and 60-day mortality (44.3 vs. 56.9%). From this auspicious beginning, but without much further published evidence, care bundles were rapidly promoted

to key planks in two international programmes. The Institute for Healthcare Improvement integrated them into each of the 100,000 Lives (2004) and 5 Million Lives (2006) Campaigns that were aimed specifically at increasing safety and transforming the quality of hospital care [3]. This covered clinical conditions, such as respiratory and cardiac failure, and included several types of sepsis. Care bundles were also an integral part of the "Surviving Sepsis Campaign" that aimed to improve survival from severe infection by 25% by 2009. Its mechanism was to implement a 6-h resuscitation bundle including early goal-directed therapy followed by a first 24-h management bundle [4, 5]. Each of these programmes was successful, and with their achievements the perceived value of sepsis care bundles has quickly escalated. There is now evidence demonstrating the benefits that sepsis care bundles bring to particularly ventilatorassociated pneumonia [1, 6-8], catheter-related bloodstream infections [6, 9] and the 6- and 24-h sepsis care bundles [10]. However, there have also been publications demonstrating that the care bundles are not universally successful.

A sepsis bundle approach was evaluated in adult severe sepsis with positive blood cultures [11]. No one received all bundle elements within the time limits, and only 52% got broad-spectrum antibiotics within 3 h of presentation. It was concluded that the early recognition and resuscitation of septic patients are unreliable and the capacity to deliver this limited. This last was supported by a recent audit that demonstrated that most acute medical units in the UK did not have the resources to deliver the 6-h care bundle [12]. Even in studies with positive results, cautionary findings are described. Whilst showing statistically significant benefits, the Gao et al. [10] study only achieved a 52% 6-h sepsis bundle compliance rate, whilst for the 24-h bundle this was 30%. A Spanish study that demonstrated improved guideline compliance and lowered hospital mortality through sepsis care bundle introduction noted that overall post-intervention process of care measure compliance remained disappointing (10.0–82.7%), and resuscitation bundle adherence returned to baseline after 1 year [13]. It is clear that sepsis care bundles are not a utopian "silver bullet" for infection management.

Care bundles ensure that strongly evidence-based clinical practice is consistently applied in a sustained pattern to all patients on all occasions. Incongruous as it may appear, the key target in bundle implementation is to change clinical practice since it recognises that on the majority of occasions, core clinical interventions are not uniformly and robustly applied to all patients. Bundles enable clinicians to more reliably deliver the best possible care against a background where every intervention carries inherent risk through its commission or omission. They are simply means improving care in a structured way. There are two essential elements. First, a bundle is made up of a small (usually three to five) number of processes that have, second, been demonstrated by the highest quality of evidence to work, so that performing them collectively and reliably will improve patient outcomes. Erosion of each of these features is a threat currently clouding bundle development. There is an increasing tendency to use the term "care bundle" loosely to cover pathways based on recommendations or good practice rather than the highest quality evidence and where there is neither support for the accumulated benefit of the individual components nor specific accountability for delivery of the complete package. These trends must be reversed so that the integrity, and hence effectiveness. of care bundles is maintained.

Bundle effectiveness comes from the excellence of the supporting evidence and its consistent comprehensive execution, with the impact being greater by performing all elements together rather than any other grouping of components. A feature of bundles needing development is the ability to recognise the relative contributions of the various elements to best enable their future evolution. Invariably bundle elements are not new, but because in normal practice they are not uniformly performed, treatment is unreliable and driven on occasion by idiosyncrasies. Bundles remove these perverse variations by constructing the elements into packages that must be followed for every patient every single time. It is this simplicity and inherent strength that have increased the

approach's attractiveness and have engendered an almost religious belief in its ever broadening applicability.

At the heart of the problems experienced in practice lie how clinicians work and think since the methodology requires their behaviour changes. A questionnaire that evaluated ventilator-associated pneumonia recommendations amongst experts found an overall 37% nonadherence rate, where compliance was unrelated to the weight of evidence [14]. The commonest reasons for nonadherence were disagreement with interpretation of clinical trials (35%) and the unavailability of resources (31.3%). Clearly simply presenting bundle recommendations to clinicians will not lead to the necessary behaviour changes to deliver successful, sustained interventions.

Credible process measurements are essential to enable positive changes in care. Measurements for improvement should be simple and easy to make so that they readily empower the teams involved [15]. Inevitably this statistical approach does not produce the rigour conventionally required in research practice and so can be seen by detractors as an opportunity to decry these processes. Adopting this stance ignores the overwhelming underlying evidence base that supports the methodology's construct as a whole. Within antibiotic prescribing, several assessments have recently been made into effective interventions [16-19]. To be successful these interventions must rest in strong process and prospective audits with intervention and feedback alongside high impact activities including education and guidelines. The most effective interventions are known to be multifaceted [20, 21]. Critically these ways of working must become the daily business rather than parallel processes open to perceptions of adding to staff burdens. This requires up-front resources to enable the changed behaviours and investment to sustain it.

Data support that sepsis care bundles have an important role in future infection management but set within overall programmes and not as singular solutions. These multifaceted programmes require investment that will be outweighed by the resultant benefits. To achieve, this clinical practice must change, which depends upon the clinicians' willingness to submit to that and adopt these new ways of working. Health-care organisations are traditionally strong in new technology and drug investments, but poor in resourcing organisational development. For sepsis care bundles to succeed this must change.

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