Care bundles in intensive care

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The bundle approach to providing medical care has become increasingly popular in recent years. A care bundle is a group of interventions which when delivered together lead to a better outcome than performing interventions individually, representing an improvement over a non-structured approach.

History

Care bundles were first developed over 20 yr ago. They have been used in a number of different medical and surgical specialities and have been used particularly extensively in cardiology. The care bundle approach to providing medical care forms part of a more general philosophical change in the way that medicine is practised. Important key elements include the development and widespread application of evidence-based medicine (on which bundles are based), the introduction of audit and performance assessment, and the introduction of guideline and protocol-based care to ensure the delivery of a minimum standard.

Interest in the application of care bundles to critical care developed in the late 1990s and early years of this century. This was fuelled by the publication of an early goal-directed therapy study in the treatment of severe sepsis and septic shock.1 Although this study is now considered controversial, it generated much interest at the time because the apparent improvement in outcomes it demonstrated came about as the result of implementation of a protocol involving a number of distinct elements which could be regarded as (or in a more general sense, delivered as) a care bundle.

Bundles were further described by Berenholtz and colleagues2 as a means of assessing quality of care. In their approach, interventions were applied which could be shown to prevent avoidable morbidity and mortality. They could further be viewed as a method of improving the processes involved in clinical care. As can be seen from this approach, care bundles have two main strands, focusing on (i) the interventions themselves and (ii) the processes of care delivery. Consequently, the care bundle is also seen as a valuable tool for audit and quality assurance. As such, it has become popular both as a management and clinical tool.

Bundles formed a key part of the ‘100 000 Lives Programme’ (2004) and the ‘5 Million Lives Campaign’ (2006) introduced by the Institute for Healthcare Improvement.3 These were aimed at increasing patient safety and improving quality of care in a variety of clinical conditions. In critical care medicine, these included sepsis, cardiac, and respiratory failure.

On the international scene, bundles have also been strongly promoted in critical care. A key example of this is the Surviving Sepsis campaign. This international collaborative initiative aimed to design and implement a care bundle approach to improve survival from severe sepsis by 25% by the year 2009. The success of all three care bundle programmes described above has led to further enthusiasm and interest in intensive care bundles for the management of a wider range of conditions in the future.

Elements of care bundles

A care bundle consists of a group of (usually) between three and five evidence-based interventions. These are related to a particular condition or event in patient care. In practice, the evidence base relating to much of intensive care medicine is still evolving and, at the present time, is insufficient for all elements of care bundles to be level Ia evidence. Where high levels of evidence exist, these are incorporated into care bundles, although many components are drawn from lower levels of evidence including expert opinion. As a result, care bundles require continuous re-evaluation and periodic updating. Interventions are grouped together in this way, on the assumption that the interventions, when executed together, result in better outcomes than would be the case if they were implemented individually.

The choice of interventions for inclusion in a care bundle is often contentious and heavily
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based on expert opinion. Each intervention should be widely accepted as good practice in its own right, and widely applicable.

A key principle of care bundles is that there should be a high level of adherence to all components. In essence, unless there is a clear reason for clinical variance, all elements should be implemented in every patient 100% of the time. Reasons for clinical variance should be clearly documented (in other words, variation from the bundle where necessary should always be a matter of positive decision, rather than a passive act of omission).

Most elements of care bundles used in critical care are delivered within the critical care environment. For bundles to deliver maximum effectiveness, it may be necessary to commence them before the patient reaches the critical care unit and to continue them out with the critical care environment. This can include periods of patient transfer to other clinical care environments such as the operating theatre or radiology suite, or after final discharge or step down from the critical care unit.

Because the bundle approach is all-encompassing, it can be used to measure and audit both matters of process and evidence-based practice. Each individual step should be capable of audit, at least on a ‘done/not done/local exclusion’ level. Care bundles are generally standardized nationally and internationally, although it may be necessary to introduce specific local variations or exclusions for a pre-defined reason. However, these would normally require a strong level of justification. For example, the presence of a spinal injury might place a restriction on compliance with the ‘30 head-up’ position required as part of the ventilator care bundle.

The audit of care bundles assesses the delivery of interventions, rather than how well these are performed. For example, it should be possible to audit whether or not all patients as part of a ventilator care bundle have received mouthwash. This audit does not consider how effectively an individual nurse performs the mouthwash, or the effectiveness of the mouthwash; simply whether or not it was done. By keeping audit measures relatively simple, the output of audit data is more likely to be robust, and the care bundle more likely to be both implemented and effective. In audit terms, a care bundle has only been complied with when every intervention is completed, or a particular intervention or step has been positively excluded for a clearly documented reason. Omission of one or more steps without clear documentation as to the reasoning (even if such a reason exists) represents a ‘failure of care’. Key points in the description of the care bundle are summarized in Table 1.

### Do care bundles work?

To assess whether care bundles work, we will consider, point by point, the elements of the underlying theory and whether this holds up in practice. First, the care bundle approach requires that all appropriate patients in a specified group receive all elements of the care they need (each part of the bundle) and that this in turn improves the overall level of care. This is based on the assumption that a uniform process for delivering evidence-based ‘high impact’ interventions should reduce unwarranted variations in care. It should prevent unrecognized omissions of clinical care, as a result of human error or local variations in practice, which in turn should reduce morbidity and mortality. The combination of elements of the care bundle would therefore be expected to convey:

- Direct benefit to the patient
- Shorter intensive care stay
- Reduced financial cost
- Improve resource utilization, and therefore, benefit to other patients outside the scope of the care bundle

Care bundles are not ‘set in stone’. Indeed, it is part of the underlying philosophy that the existence of a care bundle should in itself encourage review of the evidence, together with the incorporation of new evidence and appropriate modification of clinical care guidelines. This process encompasses staff education in best practice.

The theory behind these assumptions has been well validated in several clinical studies. The body of work by Pronovost and colleagues relating to reductions in catheter-related sepsis has clearly demonstrated the effectiveness of a care bundle approach in reducing venous catheter-related complications in critical care. In this work, the authors were able to demonstrate that adherence to the evidence-based recommendations from the Centres for Disease Control and Prevention (CDC) resulted in a significant reduction in catheter-related infection. Elements of the bundle included guidance on hand washing, the use of full aseptic technique for central venous catheter insertion, and the use of chlorhexidine solution for skin preparation. Additionally, the approach minimized the use of the femoral route and mandated that lines should be removed as soon as possible once their presence was no longer necessary. Much of the evidence supporting the elements of these care bundles is lower level evidence, based on small studies and observational data. Nevertheless, the combination of measures together resulted in a dramatic reduction in infection rates per 1000 catheter days from 2.7 to 0 within 3 months of implementing the change. After a further 18 months, infection rates remained at 66% of baseline. As a result of the success of that programme, a similar programme, together with accompanying audit, has been rolled out internationally (‘matching Michigan’).

There are numerous other examples. In a single-centre study recently published by Bouadma and colleagues, the incidence of ventilator-associated pneumonia was reduced by 51% over a 2 yr...
period after the introduction of a ventilator care bundle. Key elements of the bundle included hand hygiene, the wearing of gown and gloves while performing interventions, adoption of a semi-recumbent position (30° head-up tilt), meticulous attention to correct tracheal cuff pressure, elimination of unnecessary placement of nasogastric tubes, care to avoid gastric distension, good oral hygiene, and avoidance of tracheal suctioning other than when essential.

Perhaps the best-known example of a care bundle in use throughout most intensive care units in the developed world is the sepsis care bundle, based on the Surviving Sepsis campaign. This collaborative international campaign promotes information through its website and through publication of recommendations in the major critical care journals. This initiative has been widely criticized because a number of the interventions are based on lower levels of evidence and expert opinion and because of a perceived potential commercial conflict of interest relating to sponsorship of the original campaign. Despite this, the care bundle has been widely adopted and highly successful. The specific elements of the bundle include definitions, resuscitation, and ongoing management guidelines for severe sepsis and septic shock (Table 2).

Levy and colleagues evaluated the effectiveness of the surviving sepsis guidelines. In their study, the authors considered 165 sites across the USA, Europe, and South America where the surviving sepsis guidelines had been introduced. In total, there were 15,022 subjects with data collection between January 2005 and March 2008. At the beginning of this time, whole bundle compliance was 10.9%, but improved to 31.3% by the end of the second year. Compliance with the management bundle improved from 18.4% to 36.1%. This was associated with (whether causally or otherwise) a reduction in unadjusted hospital mortality from 37% to 30.8% over 2 yr ($P=0.001$). The adjusted mortality odds ratio was shown to improve according to how long the site to which it related has been enrolled in the Surviving Sepsis campaign. This resulted in an absolute reduction in the adjusted odds ratio for mortality of 0.8% per quarter, totalling 5.4% over a 2 yr period. The authors recognize that although the introduction of the Surviving Sepsis campaign care bundle was not necessarily the direct cause for the mortality reduction, across individual units, there was an association with improved bundle compliance and improved clinical outcomes.

In the UK, the implementation of care bundles has been supported through the critical care networks. Although this means that there is a small regional variation, it also provides a mechanism for auditing compliance with bundles. An online audit published by Lagan and colleagues in August 2008 suggested that 96% of the units were using a ventilator care bundle and 68% of those units achieved 80% or better compliance. However, there were insufficient data on patient outcomes to document whether or not there has been an improvement. Similarly, 53% of the units were using the surviving sepsis resuscitation bundle and 60% the surviving sepsis management bundle. Compliance with these bundles was poorer than with the ventilator care bundle, and again, no clinical outcome data were presented. Seventy-one per cent of the units reported using the ‘saving lives’ central venous central venous catheter insertion bundle. Forty-five per cent of the units achieved 100% compliance (perhaps because of the Matching Michigan programme, driven by the Department of Health), but again, no clinical outcome data were available (Table 3).

### Table 3 The Ventilator Bundle—introduced by Patient Safety First, a national campaign launched in June 2008

| Elevation of the head of the bed to between 30° and 45° |
| Daily ‘sedative interruption’ and assessment of readiness to extubate |
| Peptic ulcer disease prophylaxis |
| Venous thromboembolism prophylaxis |

### Conclusions

Based on international evidence, there is a strong case for widespread implementation of care bundles in critical care medicine. There are a large number of reports in the literature evaluating the success and effectiveness of critical care bundles; where these have been implemented with a high degree of compliance, there have been associated reductions in morbidity and mortality. In the UK, however, there is something of a paucity of data. It also seems to be the case that while some units have adopted care bundles with enthusiasm, uptake has been patchy, and overall compliance is variable. One approach to improving compliance is to include a care bundles checklist on ‘end of the bed’ charts in critical care units. Another approach is to make bundles a quality mark with financial implications, and incorporate care bundle compliance into the commissioning process. This approach is in line with the current philosophy of health-care
commissioning in the UK, but does not necessarily represent the international perspective. In conclusion, care bundles seem, as far as the limited evidence is able to assess, to have been effective and are here to stay. It remains the responsibility of the critical care community to further develop, refine, and update bundles in the light of evolving clinical evidence.

Declaration of interest

None declared.

References


Please see multiple choice questions 25–28.