

Improving the quality of care of the critically ill patient: Implementing the care bundle approach in the ICU



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The delivery of quality patient care remains a challenge in critical care services, especially where resources are stretched and the health care system fragmented. Integrating sound theory with clinical practice can benefit from the introduction of valid, reliable research findings at the bedside for the benefit of the critically ill patient and the critical care team. The care bundle approach provides a practical tool to implement evidence-based practice in critical care. Care bundles were originally developed in the USA as a health care improvement strategy, and are best described as groups of evidence-based practice interventions. The theory underpinning care bundles is that patient outcome improves when several evidence-based interventions are grouped together in a single protocol. The consistent implementation of evidence-based practice has been proven to improve outcome and reduce costs significantly. Several care bundles have been developed and tested. Not all are exclusive to critical care, but four that are specific to critical care are briefly described in this review as an introduction to the care bundle approach.

The search strategy included articles published in the medical and nursing critical care literature from 2001 to 2007, bar one or two older but relevant articles, using the key words care bundles, quality and evidence-based practice.

Providing health care to the critically ill patient is generally associated with compassion, competence and excellent care. Excellent care is dependent on the quality of care delivery. 'The term "**quality**", traditionally regarded as related to products, should also be applied to the **care** given in an intensive care unit. ... Intensive care standards can only be maintained by quality control of ICU facilities, activities and results. Unit directors should therefore be aware of developments in quality control of intensive care standards and should become involved in outcome analysis in the interests of their patients, their units and their hospital finances.'¹ These words were penned by Linton and Frutiger in the *SAMJ* of May 1996. Not much has changed in the intervening 11 years with regard to the concept, but in 2007 the capacity to do so has become a real challenge. Linton and Frutiger¹ go on to say that 'The introduction of quality management principles into the field of medical care was advanced by the work of Donabedian [reference 2], who identified that overall quality in medicine should include three aspects: Structures, Processes and Results (outcomes). For each of these aspects, distinct instruments to assess and maintain quality are suggested. The appropriate instrument for **Structural quality** is a standard. **Process quality** is ensured by formulating and implementing guidelines and protocols. **Outcome quality** is assessed by the use of specific indicators such as mortality prediction models, incidence of re-

admission, post-admission morbidity, etc. Medical (and nursing) audits are used to continuously improve the processes and outcome.' Health care improvement requires a collaborative effort by both managerial and clinical staff to implement and sustain initiatives to achieve quality patient care.

The development of evidence-based clinical practice since the early 1990s has initiated a paradigm shift with the realisation that 'health care interventions, no matter how commonsense or physiologically sound, often lack benefit and sometimes can even cause harm'.³ Evidence-based practice requires the integration of individual clinical expertise and the best external evidence.⁴ Pronovost *et al.* stated in 2004 that 'the greatest opportunity to improve outcomes for patients over the next quarter century will probably come not from discovering new treatments but from learning how to deliver existing effective therapies'.⁵ This article explores the potential of doing exactly that by using the care bundle approach to improve the quality of care of the critically ill patient.

Striving for quality

Much of the development of quality of care concepts and the relevant tools related to the critically ill patient has taken place at an international level, particularly in the UK,^{6,7} USA,^{5,8} Canada,⁹ New Zealand and

Australia.^{9,10} In South Africa¹¹ critical care service delivery is fragmented, supplied by both private and public (at both secondary and tertiary level hospitals) sector components and to a population ranging from the neonate to the geriatric. Some of the concepts developed internationally seem to have been introduced into a few South African health care systems in selected areas, but this occurs in an unco-ordinated and *ad hoc* fashion as no national standard of care has been set or mandated for the delivery of critical care services.

In general, various measures have been put in place in the pursuit of quality patient care over time, but they have the potential to create some confusion owing to similar terminology and overlap of purpose. Over the past number of years that critical care services have been provided, health care institutions have developed quality standards with which both the hospital and its practitioners should comply regarding the provision of quality service, such as the Joint Commission International Accreditation (JCIA) of the USA.¹² In South Africa, the Council for Health Services Accreditation of Southern Africa (COHSASA)¹² fulfils such a role. As COHSASA puts it, 'healthcare facilities standards are statements that define the key functions, activities, processes and activities required for departments to provide quality services'.¹² An example would be health care management standards that focus on patient safety.¹² Standards have also been set for critical care nursing practice.^{13,14} Critical care nursing standards can be defined as 'statements that describe desirable and achievable expectations regarding critical care nursing practice, e.g. an interdisciplinary health care team approach to patient care that achieves and maintains an optimal level of functioning, or supports a peaceful death is promoted in the critical care unit'.¹³ Procedure manuals¹⁵ have been compiled to provide detail required for specific critical care nursing practical procedures such as endotracheal tube suctioning. The latter are often associated with evaluation tools¹⁶ that can measure the competence of the practitioner performing this procedure. Hospitals have set up policies, i.e. hospital-specific managerial decisions relating to specific matters such as restraint of patients, administration of specific medications or the management of ICU beds.¹⁷ Protocols have been developed detailing a standard method of care delivery such as the initiation of enteral nutrition in the critically ill patient, and are often graphically illustrated by means of an algorithm posted at the patient's bedside. These should be based on an evidence-based guideline¹⁸ in the interests of practising sound, research-based patient care. Sackett *et al.* describe evidence-based medicine/practice as 'the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients, namely integrating individual clinical expertise with the best available external evidence from systematic research'.⁴

Critical care services should primarily aim to deliver quality care to critically ill patients who are admitted to the service, irrespective whether the service is in the private or public sector, or whether the patient is an adult, child or neonate. Ideally, medical directors, nurse managers and business managers should strive to provide quality patient care utilising a multi-disciplinary approach that implements evidence-based clinical practice through team work.^{6,8} Angus and Black⁸ state that 'institutional and healthcare system approaches complement bedside strategies to improve care of the critically ill'. Various clinical practice guidelines have been developed internationally to facilitate the implementation of both medical and nursing practice that is evidence-based. A short summary of key points in the form of a protocol or algorithm provides a useful bedside tool in the practical implementation of the guideline.

A further step in this process is the collection of a number of clinical practice guidelines in the format of a care bundle that is specific to a particular aspect of patient care. A bundle is defined by the Institute for Healthcare Improvement (IHI) in the USA¹⁹ as 'a collection of processes needed to safely and effectively care for patients undergoing particular treatments with inherent risks (e.g. mechanical ventilation); a grouping of several scientifically grounded elements essential to improving clinical outcomes' (quoted by the Joint Commission on Accreditation of Healthcare Organizations¹⁹). The Commission notes that several interventions are therefore bundled together, and when combined, significantly improve patient outcomes.¹⁹

Ultimately, the aim of all these measures is to ensure that quality patient care is provided to the critically ill patient, with each of these tools having a place in the care provision tool kit. This article will specifically address the utilisation of care bundles as a tool in improving patient care in the ICU.

Care bundles

Care bundles are best defined as groups of evidence-based practice interventions,²⁰ directed at the management of specific disease processes with the aim of improving outcome. Cinel and Dellinger state that 'bundles capture a set of quality indicators that precisely evaluate a hospital's performance with respect to disease care',²¹ maintaining that 'this allows hospitals to have an objective assessment of the quality of care being rendered at their institutions and teach interested teams how to improve performance to reach best practice, as defined by clinical guidelines'.²¹ Fulbrook and Mooney²⁰ define the use of care bundles in critical care as 'a practical approach to evidence-based practice', describing the bundles as groups of evidence-based practice interventions. They note that in a climate where clinical practice is subject to clinical governance, it is particularly pertinent that

evidence-based decision-making and knowledge-based practice is routine. In the UK, Government directives require that those working in critical care environments examine their practice to ensure that it is evidence-based and of the highest quality.²⁰

The concept of care bundles was developed in 2002 by the IHI during an innovation project aimed at developing the Idealized Design at Intensive Care Unit (IDICU).¹⁹ Fulbrook and Mooney²⁰ note that the original underpinning work was carried out at the Johns Hopkins University by Berenholtz *et al.* in 2002. They reviewed 35 years' worth of critical care literature (1965 - 2000) and critically analysed the strength of evidence of interventions that could prevent avoidable morbidity and mortality in the ICU. They identified only six evidence-based interventions that would improve ICU outcome, and four of these were later clustered together to form the ventilator care bundle. In an effort to improve the care of ventilated patients, and reduce both the risk and cost of ventilator-associated pneumonia, the IDICU committee identified these four key components of clinical care (discussed later) that had been shown to be effective in randomised clinical trials. The components formed the first of the care bundles which were developed to help health care providers to more reliably deliver the best possible care for patients undergoing particular treatments with inherent risks.²²

Carol Haraden, IHI Vice President and patient safety expert, defines a bundle as 'a structured way of improving the processes of patient care and patient outcomes: a small, straightforward set of practices – generally three to five, that when performed collectively and reliably, have been proven to improve patient outcomes'.²² She goes on to explain that 'the power of the bundle comes from the body of science behind it and the method of execution – viz. consistency. The changes in the bundle are not new, they are in fact well-established best practices, therefore the bundle ties together the changes into a package of interventions that people know must be followed for every patient, every time. A bundle is therefore a specific tool with clear parameters, that has a small number of elements that are all scientifically robust, that when taken together create much improved outcomes.'²² In order to have a good outcome all the elements of the bundle have to be provided. The changes or elements of the bundle are all scientifically robust, viz. based on the findings of randomised controlled trials (RCTs), i.e. level I evidence in the hierarchy of evidence.^{20,21} The bundle focuses on how to deliver the best possible care, providing the steps of evidence-based care provision by the practitioner. The bundle requires an all-or-nothing approach to ensure success, as well as implementation at a specific time and in a specific place.²² This implies the collaboration of all team members to ensure the successful implementation of the care bundles in order to achieve quality patient care. The IHI maintains that

'by implementing a system-wide model of care, and developing and maintaining a skilled, coordinated, and collaborative care team, organizations can establish new systems of ICU care that will produce better clinical outcomes, fewer adverse events, much higher levels of patient and family satisfaction, and lower costs'.²²

Outcome measures that can indicate the quality of patient care relate to length of stay in the ICU, number of ventilator-dependent days, length of hospital stay, number of complications or complaints, ICU mortality, and overall hospital mortality,⁵ taking the patient's demographic data, pre-morbid health status and co-morbid diseases into account. Reducing the risk of infections in particular is an effective tool in reducing the rate of complications in the critically ill. This is a group especially prone to infections, and reduction of these levels leads to improved quality of patient care. This strategy has been employed by both the UK National Health Service (NHS) in their 'Saving Lives' programme, and in the USA with the '100 000 Lives Campaign' in an effort to reduce health care-associated infections,²⁴ which are extremely costly for both health care institutions and patients. Robson, quoting from a 2005 Department of Health report, states that health care-associated infections cost the NHS approximately £1 billion each year.²⁴ It is therefore in the interests of both patient and provider to employ interventions that have been proven to reduce this risk. Both these programmes use a care bundles approach that is of particular interest to critical care nurses familiar with the use of care bundles in improving patient care.²⁴ It is important to note that the care bundle approach must be applied with clinical judgement, according to patient-specific needs.

Types of bundles

The central line bundle

Haraden²² describes this bundle as 'a set of five steps to help prevent catheter-related blood stream infections, viz. deadly infections that can be introduced through an intravenous (IV) line in a patient's vein supplying food, medications, blood or fluid'. The steps consist of the following commonsense tasks:

1. Using proper hand hygiene
2. Maximal barrier precautions
3. Properly cleaning the patient's skin, viz. chlorhexadine skin antisepsis
4. Optimal catheter site selection, with the subclavian vein as the preferred site for non-tunnelled catheters
5. Daily review of line necessity, with prompt removal of unnecessary lines.

Use of the IHI's central line insertion checklist at the time of each line placement helps ensure that all components of the central line bundle are met each and every time.¹⁹

Details of the components included in the central line bundle are described in the *Guidelines for the Prevention of Intravascular Catheter-Related Infections* published by the Centers for Disease Control and Prevention (CDC) of the US Department of Health.²⁵

The surgical site infection bundle

Surgery generally carries a risk of infection, which can prolong a patient's hospital stay. This bundle therefore involves:

1. The appropriate use of (prophylactic) antibiotics (immediately) before and after surgery (for a short period)
2. Stopping the practice of using razors (cause nicks that invite infection) to remove a patient's hair before surgery
3. Keeping the patient warm during surgery
4. Monitoring (and controlling) the patient's blood sugar level after surgery.²²

The ventilator care bundle

Ventilator-associated pneumonia (VAP) is a serious form of pneumonia that patients on ventilators may develop.²² The ventilator bundle consists of four steps:

1. Elevating the head of the patient's bed to between 30° and 40°
2. Daily sedation vacation (interruption) and daily assessment of readiness to extubate
3. Gastric ulceration prophylaxis
4. Deep-vein thrombosis (DVT) prophylaxis (unless contraindicated).

The first two components are directed at preventing VAP while the latter two components are directed at preventing other complications associated with mechanical ventilation. The IHI has noted an average 45% decrease in VAP in a recent collaborative improvement project.²⁶ It is useful to use the IHI's ventilator care bundle checklist to track compliance with this bundle.¹⁹

The sepsis care bundles

There are two separate severe sepsis bundles, viz. the sepsis resuscitation bundle and the sepsis management bundle.¹⁹

The following are the components of the sepsis resuscitation bundle, which should be initiated immediately and completed within 6 hours in patients with severe sepsis or septic shock:

1. Serum lactate measured
2. Blood cultures obtained before antibiotic administration
3. From the time of presentation – broad-spectrum antibiotics administered within 3 hours for emergency department (ED) admissions and 1 hour for non-ED ICU admissions

4. In the event of hypotension and/or lactate of >4 mmol/l:
 - a. Deliver an initial minimum of 20 ml/kg of crystalloid (or colloid equivalent)
 - b. Apply vasopressors for hypotension not responding to initial fluid resuscitation to maintain mean arterial pressure (MAP) of 65 mmHg
5. In the event of persistent hypotension despite fluid resuscitation (septic shock) and/or lactate >4 mmol/l:
 - a. Achieve central venous pressure (CVP) of 8 mmHg
 - b. Achieve central venous oxygen saturation (S_cvO₂) of >70%.

The following are the components of the sepsis management bundle, which should be initiated immediately and completed within 24 hours for patients with severe sepsis or septic shock:

1. Low-dose steroids administered for septic shock in accordance with a standardised ICU policy
2. Blood glucose control maintained above the lower limit of normal but <8.3 mmol/l
3. Inspiratory plateau pressures maintained <30 cm H₂O for mechanically ventilated patients (essentially lung protective strategies)
4. The use of drotrecogin alfa (activated) is currently not recommended for routine use, and should only be considered in very select cases.

The severe sepsis bundles were developed from the practice guidelines of the Surviving Sepsis Campaign, published by the European Society of Intensive Care Medicine and the Society of Critical Care in 2004.^{19,28}

Benefits

Ventilator care bundle

Crunden *et al.*²⁷ conducted a study to evaluate the impact of the implementation of the ventilator care bundle a year after its introduction in a general ICU in the UK. They found that 'Care bundles encourage the consistent and systematic application of evidence-based protocols used in particular treatment regimes'. Their findings revealed that the introduction of the ventilator care bundle significantly reduced the length of ventilation and the ICU LOS. In an improvement report cited by the IHI, Apostolakis *et al.*²⁶ reported that the introduction of the ventilator care bundle in the medical, surgical and cardiovascular intensive care units of their hospital in New York resulted in a significant reduction in VAP rates. Resar *et al.*²⁹ reported a 44.5% reduction in VAP in units that implemented a care bundle approach and consistently collected data on ventilator bundle adherence and VAP rates. These reductions translate into significant cost savings on a per patient basis for the health care institution.

Sepsis bundle

Gao *et al.*³⁰ conducted a prospective observational study to evaluate the impact of compliance with the 6-hour and 24-hour sepsis bundles on hospital mortality in patients with severe sepsis or septic shock admitted to two of their NHS hospitals. They found that non-compliance with the 6-hour sepsis bundle was associated with a more than twofold increase in hospital mortality, while non-compliance with the 24-hour sepsis bundle resulted in a 76% increase in risk of death in hospital. Shorr *et al.*³¹ performed retrospective analysis of a before-after study testing the economic implications of an evidence-based sepsis protocol based on the recommendations of the Surviving Sepsis Campaign published by Dellinger *et al.* in 2004.²⁸ The setting of their study was the emergency department of an academic tertiary care hospital in the USA and the patients selected had presented with septic shock. Their findings revealed that 'the use of a sepsis protocol resulted not only in improved mortality, but also in substantial savings for the institution and third party payers, providing a potential means for enhancing resource use while containing costs'.³⁰ Cinel and Dellinger (the latter being first author of the Surviving Sepsis Campaign) reviewed the impact on delivery of care in severe infection following the evolution and implementation of guidelines.²¹ They caution that 'guidelines themselves do not lead to process change', and suggest 'that the change-bundle approach to performance improvement, which is guideline-based, is the key to change in practice, first with measurable process change and then with outcome change, with the SSC/IHI sepsis change bundles being an excellent example of progress along these lines'.²¹

Implementation of the care bundles

A care bundle is therefore a small but critical set of processes all determined by level I evidence which must involve all the elements of each bundle, as described by Haraden.²² It is clear that the implementation of the bundles requires a team effort, with comprehensive assessments needing to be performed by both medical and nursing staff on a daily basis. Early recognition of potential infections and early initiation of the appropriate measures requires continuous monitoring, critical thinking, surveillance skills, and the prescription and administration of the correct medication. The bundle is therefore the responsibility of the entire team to ensure accountability and continuity of implementation, which should be checked periodically e.g. on the daily unit round. Checklists of tasks can be utilised to facilitate implementation of a bundle if appropriate, but cannot replace the bundle.

Care bundles provide a method for establishing best clinical practice that is evidence-based, relatively simple and inexpensive to implement, and easily audited.²⁰ Fulbrook and Mooney²⁰ caution however that implementation of the bundles does constitute a change in practice and should be introduced carefully. Implementation requires effective communication, with clear explanations of the change, the new process, and the benefits of the new process. They recommend small step-change methodology to introduce the care bundles into practice. Clinical discussion groups provide a vehicle to introduce changes in practice. The potential for standardising practice, simplifying work procedures for staff and improving patient care provides an incentive to comply with the bundles. Various tools, such as the checklists, are available to help institutions get started with the implementation of the bundles. A collaborative approach by several units can prove useful when introducing the bundles to a particular institution. Fulbrook and Mooney²⁰ emphasise the importance of a whole-team approach to clinical improvement work, involving both clinical staff and service planning staff to ensure ownership of the care bundle and sustainable implementation. Agreement must be reached on all care bundle components and protocols by the multidisciplinary team members. This process could be driven by a clinical nurse specialist. It is noted that the individual components are evidence-based current practice and therefore not new concepts; however the clustering of the individual components into a care bundle is a new concept. It is a process that requires audit of the new intervention, and initial establishment of baseline measures for purposes of comparison is important. These include the outcome measures noted such as ICU mortality, length of stay in the ICU, etc., but also require audit of the process with regard to compliance of practice. Run charts of the results have proved to be useful in keeping staff informed about the process.²⁰

Conclusion

The delivery of quality patient care remains a challenge in critical care services, especially where resources are stretched and the health care system fragmented. Integrating sound theory with clinical practice can benefit from the introduction of valid, reliable research findings at the bedside for the benefit of the critically ill patient and the critical care team. The care bundle approach provides a practical tool to implement evidence-based practice in critical care. Several care bundles specific to critical care that have been developed and tested have been described. These bundles and their related tools have been developed for the benefit of all critically ill patients, and research into their value continues. It is the opinion of the author and the Critical Care Nursing Forum of the Critical Care Society of Southern Africa that it is time

to consider implementing the care bundles in all the critical care units across South Africa in an effort to provide standardised quality care to the critically ill patients admitted to our units.

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