Care bundles: the holy grail of infectious risk management in hospital?
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Introduction
The Institute for Healthcare Improvement (IHI) developed the concept of ‘bundles’ to help healthcare providers to improve the reliability of delivery of essential healthcare processes [1]. The impact of a bundle depends both on the evidence that supports the recommended care processes and on the implementation and spread of its recommendations. Not all clinical situations and conditions require a bundle, and a bundle will not improve quality of care if its development and application are misguided. In this review, we discuss the design, implementation and testing of care bundles designed to improve the management of sepsis and the prevention of healthcare-associated infections.

What is a bundle?
The concept of care bundles has emerged from the acknowledgement that healthcare delivery is too dependent on individual clinicians’ knowledge, motivation and skills, with the result that only about 50% of patients receive the recommended care [2]. One explanation is that processes in healthcare are rarely designed to meet specific, articulated reliability goals [2,3]. A care bundle is a small set of practices that have been individually proven to improve patient outcomes and that should be performed together for every patient every time. We describe how bundles should be designed, implemented and evaluated with measurement designed for quality improvement rather than research or judgement.

Purpose of review
A care bundle is set of four or five processes that each individually improve patient outcome and that should be performed together for every patient every time. We describe how bundles should be designed, implemented and evaluated with measurement designed for quality improvement rather than research or judgement.

Recent findings
A systematic review concluded that the relative risk reduction associated with the introduction of a sepsis bundle exceeded 25%, and absolute risk reduction exceeded 9% in all studies. The number needed to treat to save one life in each study population ranged from three to 11. Bundles for the prevention of infections have focused on ventilator-associated pneumonia and catheter-associated bloodstream infections in the ICU. The most persuasive evidence of effectiveness comes from multicentre studies, but results from single ICUs provide valuable insights into how bundle implementation fits within a broader quality improvement strategy.

Summary
Care bundles can be a powerful driver for improving the reliability of delivery of evidence-based care and patient outcomes. It remains to be seen whether the success that has been achieved in acute admissions and ICUs can be reproduced in general wards.

Keywords
bloodstream infections, care bundle, healthcare-associated infection, quality improvement, sepsis, ventilator-associated pneumonia
VAP, which only started to decline 3 months later after the introduction of a process measurement program that measured daily compliance with the bundle [6]. To avoid confusion, we recommend that the term bundle is not used to describe implementation strategies that include more than one component, these should be called multifaceted interventions [7] rather than ‘bundled behavioural interventions’ [8].

The following steps have been recommended for the development of a bundle, to combine the best of medical science and improvement science [1,4]:

1. Identify a set of four to six evidence-based interventions that apply to a cohort of patients with a common disease or a common location.
2. Develop the will in the providers to deliver the interventions every time they are indicated.
3. Measure compliance as ‘all’ or ‘nothing’.
4. Redesign the delivery system to make it easy to deliver the bundle, ideally to make reliable delivery an integral part of the system.
5. Measure related outcomes to ascertain the effects of the changes in the delivery system.

What are the requirements for the inclusion of a bundle element?

Ideally, the science behind the elements of a bundle should be so well established that its implementation should be considered a generally accepted practice, with all the changes recommended based on randomized controlled trials, and therefore supported by Level 1 evidence [1,4]. However, this level of evidence is not always available for the link between processes of care and patient outcome. Accordingly, the National Quality Measures Clearinghouse (NQMC) does not stipulate that trial evidence is required for a quality measure to be valid. Evidence may consist of ‘a clinical practice guideline or other peer-reviewed synthesis of the clinical evidence’, as well as ‘one or more research studies published in a national library of evidence science [9].

Even when trial evidence for the link between a process of care and outcome is available, knowing that something works in another institution does not mean it will work in ours. It is important to remember that the key question in quality improvement is whether an intervention improves our quality of care now [10*]. The potential impact of an intervention can be considered in terms of five dimensions:

- **Reach**: What proportion of the target population participated?
- **Efficacy**: What is the success rate if implemented as in protocol?
- **Adoption**: What proportion of target hospitals/practices clinicians adopts it?
- **Implementation**: To what extent is the intervention implemented as intended/per protocol?
- **Maintenance**: To what extent is the program sustained over time?

The impact of an intervention (impact = reach × efficacy) is filtered through the organizational dimensions of adoption, implementation and maintenance [10**,11]. The influence of each of these dimensions on the effectiveness of a bundle will vary greatly between hospitals, so local adaptation of bundle elements and/or implementation strategies will be required.

With regards to the level of evidence behind the chosen bundle elements, it is very important that this is made clear, particularly when spread to other institutions is planned. Good examples of this are the Surviving Sepsis Campaign (SSC) severe sepsis management guidelines [4,12] and the Scottish National Audit Project on community-acquired pneumonia (SNAP-CAP) [13]. An unusual, but helpful, feature of the SNAP-CAP evidence review is that it includes discussion about why two care processes were not included in the bundle [13].

Bundles should be expected to evolve over time because of new evidence and focusing on the aim of improvement (Table 1). These five care bundles for ventilated patients only have one common element: elevation of the head of the bed [6,14,15*,16,17]. Three of the reasons are clear. First, the original IHI ventilator bundle was designed to improve the daily care of patients who were being ventilated, not just to prevent VAP [5,17], whereas more recent VAP bundles have omitted deep venous thrombosis (DVT) prophylaxis in order to focus on prevention of VAP [6,14,15*,16]. Second, the more recent VAP bundles [14,15*] have omitted stress ulcer prophylaxis but included drainage of oropharyngeal secretions as new evidence has been collected and published [18,19*]. Third, two of the bundles include hand hygiene as one of the care processes for prevention of VAP [6,15*], whereas two of the other VAP bundles were part of broader improvement work in the ICU, in which hand hygiene was an expected component of care for all patients and was measured separately [14,16]. However, it would be helpful if documentation of care bundles always included some comparison with published bundles with explicit discussion of why some care processes have not been included. For example, two of the bundles apparently do not include sedation or weaning [6,15*]. Is this true and if so why was sedation and weaning omitted from these VAP bundles?
Implementation through measurement and tests of change

Successful implementation, as with all quality improvement, requires engagement with all the staff involved in its delivery. Measures for improvement must be designed to provide just enough data to assess the reliability of practice and must be sustainable by frontline staff without additional resource [20]. Although this study is over 10 years old, it remains important because of the clear distinction between the information needed for quality improvement in comparison with research or accountability. This distinction is vital to engaging with frontline clinical staff as drivers for change (Table 2).

Completion of each bundle element and of the whole bundle must be measurable as ‘yes or no’ or ‘completed or not completed’ [1, 4, 21]. Compliance with the bundle means completion of every component, with no score given for partial completion. The use of rapid, repeated tests of change has been described in detail for the implementation of the IHI ventilator bundle in one ICU (Table 3 [22]).

Standardization of the care processes into a bundle should be expected to reach a very high level of reliability. A realistic first step is to aim for 80 or 90% success rate, then identify and mitigate defects from the first step in order to achieve more than 95% reliability [2]. Experience with care bundles shows that these levels of reliability can be

Table 2 The differences between data for improvement, judgement and research in terms of aim, study design, analysis and dissemination

<table>
<thead>
<tr>
<th>Aim</th>
<th>Improvement</th>
<th>Judgement</th>
<th>Clinical research</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test bias</td>
<td>Observable, sequential</td>
<td>No test</td>
<td>Blinded, one big test</td>
</tr>
<tr>
<td>Sample size</td>
<td>Just enough to assess reliability, usually 10 observations if the target is more than 95% reliability</td>
<td>100% of relevant data</td>
<td>Collect as much data as possible, just in case</td>
</tr>
<tr>
<td>Analysis: is change an improvement?</td>
<td>Run chart with predefined target and annotations to explain drivers for change</td>
<td>No change, data are usually displayed as a normative comparison (e.g. league table)</td>
<td>Statistical test to determine how likely it is that change happened by chance</td>
</tr>
<tr>
<td>Confidentiality and dissemination of information</td>
<td>Data only for stakeholders; consent is not required from individual patients or staff for data collection but the data should only be made public if the subjects agree</td>
<td>Publicly accessible information</td>
<td>Subjects protected through written consent based on information agreed with an independent Research Ethics Committee</td>
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</tbody>
</table>

DVT, deep venous thrombosis.
achieved and can yield measurable improvements in patient outcome. For example, improvement of reliability of a central line care bundle from 80% to more than 95% in one ICU was followed by near abolition of line-related infections [16]. Similarly, data from 35 ICUs that implemented the IHI ventilator bundle showed that the most consistent reduction in VAP occurred in six ICUs that achieved more than 80% improvement in adherence with the bundle [17].

Data about the impact of quality improvement interventions should be presented as run charts that clearly document change over time [23]. Annotation of run charts can be used to document the effect of multiple drivers for change, as most interventions have multiple components [16] (Fig. 1). This run chart clearly shows the contribution of an organizational change (multidisciplinary rounds and the appointment of an ICU Medical Director to lead quality improvement) to the reduction of adverse events in one adult ICU over 2 years. The implementation of bundles to reduce hospital-acquired infection was just one of the changes that were implemented (Fig. 1). For interventions that aim to reduce healthcare-associated infection, it is important to document all of the key infection control processes, including those that are not included in the intervention [24].

**Figure 1  Run chart of the number of adverse events per ICU day over 2 years and the impact of a multifaceted strategy for quality improvement**

<table>
<thead>
<tr>
<th>Cycle</th>
<th>Date</th>
<th>Test of change</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>5 February</td>
<td>Test sedation vacation with one patient</td>
<td>Change time of day of sedation vacation</td>
</tr>
<tr>
<td>2</td>
<td>6 February</td>
<td>Test sedation vacation with three patients</td>
<td>Document exclusions from sedation vacations</td>
</tr>
<tr>
<td>3</td>
<td>8 February</td>
<td>Test sedation vacation with all patients</td>
<td>Include documentation of exclusions as a standard element in multidisciplinary rounds</td>
</tr>
<tr>
<td>4</td>
<td>10 February</td>
<td>Test head of bed elevation with one patient</td>
<td>No modification required</td>
</tr>
<tr>
<td>5</td>
<td>14 February</td>
<td>Test head of bed elevation with three patient</td>
<td>No modification required</td>
</tr>
<tr>
<td>6</td>
<td>17 February</td>
<td>Test head of bed elevation with all patients</td>
<td>No modification required</td>
</tr>
<tr>
<td>7</td>
<td>22 February</td>
<td>Test complete ventilator bundle with one patient</td>
<td>New documentation required for completion of whole bundle</td>
</tr>
<tr>
<td>8</td>
<td>24 February</td>
<td>Test complete ventilator bundle with three patients</td>
<td>No modification required</td>
</tr>
<tr>
<td>9</td>
<td>28 February</td>
<td>Test complete ventilator bundle with all patients</td>
<td>Bundle only completed for 50% of patients, continue but aim for more than 95% reliability sustained over 4 months</td>
</tr>
<tr>
<td>10</td>
<td>14 March–14 June</td>
<td>Document bundle completion on all patients every day</td>
<td>More than 95% reliability sustained over 4 months</td>
</tr>
</tbody>
</table>

Tests of change carried out over 23 days in February 2005 and the reliability of bundle implementation was then documented with a run chart updated every week. On the basis of information from Table III and Fig. 2 of Pulcini et al. [22].
The current low academic status of quality improvement work is likely to result in clinicians who are engaged in poorly supported activities in academic medical centres leaving to become directors of quality improvement in nonteaching centres, which are investing heavily in quality improvement [27]. A fresh approach is required to measuring and documenting academic medical activity in quality improvement, particularly with respect to recognizing innovation in local quality improvement work within a single organization [27].

The distinction between quality improvement and judgement is also important. Care bundles define important processes for delivery to all eligible patients, but they are only one component in a multifaceted strategy for continuous quality improvement [16]. When the same care processes are included in centrally driven targets with financial incentives, there is serious risk of unintended consequences due to narrow focus on achieving the target at the expense of other aspects of care [28]. One clear, relevant study is administration of antibiotics to all patients with CAP within 4 h of arrival in hospital. This was adopted as a national target in the USA and resulted in excessive administration of antibiotics to patients who did not have CAP [29].

**Bundles for the management of severe sepsis and septic shock**

The survival benefit of early goal-directed therapy (EGDT) for the management of patients with severe sepsis and septic shock was first established in a randomized trial [30]. The first SSC guidelines for the management of severe sepsis and septic shock were published in 2004 [31] and have recently been updated [12]. These extensive guidelines have been condensed into two bundles: the ‘Sepsis Resuscitation Bundle’ for completion within 6 hours and the ‘Sepsis Management Bundle’, which should also begin immediately but must be done within 24 h [4].

A recent review included 12 peer-reviewed publications and 28 abstracts from 10 different countries, which evaluated EGDT as part of a sepsis quality initiative [32]. Combining the data identified 3042 patients before and 2956 after implementation of sepsis bundles. In the peer-reviewed publications, the relative risk (RR) reduction associated with the introduction of a sepsis bundle exceeded 25%, and absolute risk reduction exceeded 9%, in all studies. The number needed to treat to save one life in each study population ranged from three to 11 [32].

The success that has been achieved with improving the management of severe sepsis needs to be reproduced for management of less severely ill patients, both to improve the timeliness of effective antibiotic treatment [33] and to promote early review of antibiotic therapy in order to minimize unnecessary use [34].

**Bundles for prevention of hospital-acquired infection**

Most of the current evidence focuses on prevention of catheter-related bloodstream infections [25] and VAP [6,15,16,17] in ICUs. The evidence is most persuasive when bundle implementation is associated with improvement in outcome across multiple hospitals [17,25]. However, experience from individual hospitals can provide additional important information about how change is achieved, provided that data are presented appropriately. There is little value to reports that only provide aggregate information about processes and outcomes before and after the intervention. For example, evaluation of a ventilator care bundle as an uncontrolled before and after study [35] actually provides no evidence that change was due to the intervention [36]. In contrast, presentation of data as run charts clearly shows how change occurred over time [6,15,16].

We have selected one of these single hospital studies (Fig. 1) to show how difficult it is to quantify the direct impact of a care bundle within an ICU that is committed to change and continuous improvement. The outcome measured was the number of adverse events per ICU day, which was measured by chart review and included indicators of infection alongside indicators of other complications. This ICU implemented three infection control bundles, that is, to prevent VAP, central line infections and catheter-associated urinary tract infection (UTI). However, these were implemented after the establishment of multidisciplinary rounds and a hand hygiene protocol. The authors attributed the overall reduction in adverse events to the change in culture achieved through multidisciplinary rounds in 2002 and to the appointment of an ICU Medical Director to lead change for improvement in 2003 rather than to any one of the three bundles [16].

The successes seen with care bundles in reducing infection in the ICU have led to the development of a broader set of bundles aimed at reducing surgical site infection and infections in general wards [37]. It remains to be seen whether the same success will be achieved in these contexts in which teams are less well defined and the ratio of staff to patients is much lower than in ICU.

**Conclusion**

The answer to the question has to be no, care bundles are not the holy grail of infectious risk management. Bundles
References and recommended reading

Papers of particular interest, published within the annual period of review, have been highlighted as: • of special interest ** of outstanding interest

Additional references related to this topic can also be found in the Current World Literature section in this issue (p. 413).


3 Nolan T, Berwick DM. All-or-none measurement raises the bar on perfor- ** mance. JAMA 2006; 295:1168–1170.


This paper clearly sets out the criteria for deciding when quality improvement methods rather than clinical trials should be used to assess effectiveness.


This study shows the impact of a VAP bundle on the VAP rate per 1000 patient- days over 3 years in one paediatric ICU.


This study provides valuable quantitative and qualitative data about the variation in care and professional support for interventions to reduce risk of VAP in ICUs from the USA.


29 Meteorsky ML, Sweeney TA, Getzow MB, et al. Antibiotic timing and diagnostic uncertainty in Medicare patients with pneumonia: is it reasonable to expect all patients to receive antibiotics within 4 h? Chest 2006; 130:16–21.


Eleven peer-reviewed publications and 28 abstracts with a total of 5598 patients are reviewed. The mean absolute and RR reduction with early goal-directed therapy was greater than reported in the original clinical trial and shows that the results are generalizable across multiple healthcare settings.


This study describes the development and testing of a bundle to improve the reassessment of inpatient empirical antibiotic prescriptions over 15 months in one infectious diseases ward. This shows that bundles can be implemented success- fully in wards with lower staff to patient ratios than ICUs.

