

Innovation Series 2012

Using Care Bundles to Improve Health Care Quality

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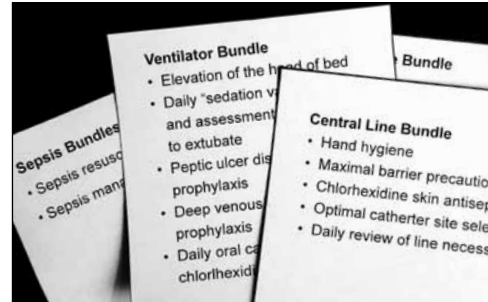
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Executive Summary

In 2001, the Institute for Healthcare Improvement (IHI) developed the “bundle” concept in the context of an IHI and Voluntary Hospital Association (VHA) joint initiative — Idealized Design of the Intensive Care Unit (IDICU) — involving 13 hospitals focused on improving critical care. The goal of the initiative was to improve critical care processes to the highest levels of reliability, which would result in vastly improved outcomes. The theory was that enhancing teamwork and communication in multidisciplinary teams would create the necessary conditions for safe and reliable care in the ICU. We focused on areas with potential for great harm and high cost, and where the evidence base was strong.

While there were many changes the teams in the initiative worked toward implementing, care of patients on ventilators and those who had central lines became a strong focus, as it satisfied all of our criteria: the evidence for the clinical changes was robust, and there was little or no controversy concerning their efficacy. Further, teams would need to find new and better ways to work together to produce reliable change and superior patient outcomes. We found that by using a “bundle” — a small set of evidence-based interventions for a defined patient population and care setting — the improvements in patient outcomes exceeded expectations of both teams and faculty.

Thus began an innovative approach to improving care: the use of bundles. This white paper describes the history, theory of change, design concepts, and outcomes associated with the development and use of bundles over the past decade. We reflect on what we have learned and make suggestions for further research and implementation of the bundle approach to improving care.

Definition of a Bundle

A small set of evidence-based interventions for a defined patient segment/population and care setting that, when implemented together, will result in significantly better outcomes than when implemented individually.

Origins of the Bundle Approach to Improving Care

In early 2001, the Voluntary Hospital Association (VHA) asked the Institute for Healthcare Improvement (IHI) to collaborate on an initiative called Idealized Design of the Intensive Care Unit (IDICU). The IDICU initiative was designed to re-examine the structure and assumptions upon which care was currently being delivered in intensive care units. Teams from 13 hospital intensive care units collaborated with VHA and IHI faculty to rethink intensive care and to discover how to achieve the highest levels of reliability in critical care processes and resultant outcomes, while at the same time introducing concepts of enhanced teamwork and communication. Processes included multidisciplinary rounds, daily goal setting, and patient and family involvement in daily patient care discussions. In spite of enthusiastic efforts by both faculty and hospital participants, initially teams made little progress in achieving high levels of reliability with care processes and improving outcomes in these intensive care units.

We studied those clinical processes that contribute to great harm and high cost, where the evidence base was strong. While the teams worked toward implementing changes in many areas, including use of blood products and pain management in the ICU, care of patients on ventilators and those who had central lines became a strong focus, as it satisfied all of our criteria: the evidence for the clinical changes was robust, and there was little or no controversy concerning their efficacy. Further, care teams would need to find new and better ways to work together to produce reliable change and superior patient outcomes. In addition, harms associated with both ventilators and central lines were commonly identified using the IHI ICU Adverse Event Trigger Tool, which teams used to identify and track harm.¹

The medical literature had described key elements of care associated with mechanical ventilation and central line placement, based on both science and experience. Although many elements related to ventilator care and central line insertions continue to involve vigorous academic debate, certain ones had a high degree of acceptance and consensus among clinicians. From these, the faculty and teams in the IDICU initiative selected the initial elements of the IHI Ventilator Bundle and the IHI Central Line Bundle — in each case, a small set of evidence-based interventions that were generally accepted by participating clinicians as elements of care that should be delivered as usual practice.

The First Two Bundles

The IHI Ventilator Bundle² and the IHI Central Line Bundle³ were the first bundles developed. The elements of the two initial bundles follow.

IHI Ventilator Bundle*

1. Elevation of the head of the bed to between 30 and 45 degrees
 2. Daily “sedation vacations” and assessment of readiness to extubate
 3. Peptic ulcer disease (PUD) prophylaxis
 4. Deep venous thrombosis (DVT) prophylaxis
- (Note: A fifth bundle element, “Daily oral care with chlorhexidine,” was added in 2010.)

IHI Central Line Bundle

1. Hand hygiene
2. Maximal barrier precautions
3. Chlorhexidine skin antisepsis
4. Optimal catheter site selection, with avoidance of using the femoral vein for central venous access in adult patients
5. Daily review of line necessity, with prompt removal of unnecessary lines

*It is important to note that the elements of the Ventilator Bundle were not designed to reduce ventilator-associated pneumonia (VAP) specifically or solely. Rather, our intent was to design processes for reliably providing care that prevents certain serious adverse events (such as gastritis and DVT) associated with the care of a patient on mechanical ventilation. (For this reason, we called it the “Ventilator Bundle” — not the “VAP Bundle.”) Accordingly, the Ventilator Bundle elements of DVT prophylaxis and peptic ulcer disease prophylaxis have very little to do with preventing ventilator-associated pneumonia; however, they have everything to do with preventing other serious adverse events experienced by ventilated patients.

“All-or-None” Measurement

With both bundles, the faculty challenged IDICU initiative participants to design local processes for achieving a high degree of reliability with all of the bundle elements. Compliance with the bundles was measured by documentation of adherence to all elements of the bundle. If all elements had been accomplished, or if an element was documented as medically contraindicated, the bundle was counted as complete for that patient. If any of the elements was absent in the documentation, no credit was given. There was no option for “partial credit.” This measurement technique for bundles — called “all-or-none” measurement — focused attention on the importance of delivering all elements of the bundle to the patient, unless medically contraindicated.⁴

Most clinicians in the participating IDICU initiative hospitals assumed that the bundle elements were being reliably performed on their patients. However, when they collected their initial data, they were surprised at the low levels of all-or-none compliance, with some ICUs finding 10 percent to 20 percent compliance at best. Participants and faculty were thus motivated to change processes in their critical care units to improve their reliability rates. It is important to note that measuring compliance with each bundle element, as well as all-or-none compliance, is the first step in building a reliable system. It both allows teams to find their most problematic areas and helps build will for improvement by acknowledging the low number of patients who receive all the care they need and deserve.

The importance of teamwork and communication in ensuring reliable and consistent care became obvious as attempts to improve compliance rates ensued. After months of reliable process design and implementation and several months of reaching high levels of all-or-none compliance with the Ventilator Bundle elements, both faculty and teams were surprised to observe reductions in VAP. This was followed by similar reductions in central line-associated bloodstream infections (CLABSI) after teams also achieved high levels of compliance with the Central Line Bundle, which was less surprising given that all elements of the bundle were designed to reduce central line infections. These reductions in the incidence of VAP and CLABSI spurred the further development and refinement of the bundle concept.

Two components were essential to the success of the Central Line and Ventilator Bundles. First, in both cases participating clinicians agreed that there was sufficient medical evidence supporting each individual element in the bundle to recommend that it be applied to most, if not all, patients; at a minimum, each element should be considered for every patient. Second, the list of elements included in the bundle was short — no more than five.

Clearly, the bundles do not represent comprehensive care. For example, mechanically ventilated patients certainly require additional care interventions beyond the five elements in the bundle; similarly, central lines have other evidence around use beyond insertion and prompt removal. The bundles were not intended to be comprehensive care; rather, they were developed to test a theory — that is, *when compliance is measured for a core set of accepted elements of care for a clinical process, the necessary teamwork and cooperation required will result in high levels of sustained performance [reliability] not observed when working to improve individual elements.*

Bundle Design

When designing care bundles, the guidelines that follow have proved helpful.

Bundle Design Guidelines

- The bundle has three to five interventions (elements), with strong clinician agreement.
- Each bundle element is relatively independent.
- The bundle is used with a defined patient population in one location.
- The multidisciplinary care team develops the bundle.
- Bundle elements should be descriptive rather than prescriptive, to allow for local customization and appropriate clinical judgment.
- Compliance with bundles is measured using all-or-none measurement, with a goal of 95 percent or greater.

The bundle has three to five interventions (elements), with strong clinician agreement.

The goal of the bundle approach is to pull together the short list of interventions and treatments that are *already recommended* and that are generally accepted in national guidelines and by local consensus of clinicians as being appropriate care for the population of focus. Including only those elements that most clinicians accept as being applicable to most patients in the population allows the team to move forward with improvement, rather than spend time debating the validity of the elements. Moreover, as the number of bundle elements increases, it becomes geometrically more difficult to achieve high compliance with the all-or-none measure. Since the intent is neither to create a comprehensive care protocol nor to include elements that vary in their applicability to individual patients, using three to five bundle elements is most successful.

Each bundle element is relatively independent.

The bundle is designed so that if one of the elements of care is not implemented for a patient, it should not affect whether other bundle elements are implemented. For example, in the Central Line Bundle, if the central line insertion site was not cleansed with chlorhexidine (one of the bundle elements), the remaining four Central Line Bundle elements still could be implemented.

The bundle is used with a defined patient population in one location.

The bundle is most successfully applied to a discrete patient population in a defined location — for example, patients on ventilators in the ICU. Involving care teams that physically work together in the same location with a defined patient population allows for strategies to achieve all-or-none bundle compliance that are not always transferable when multiple teams across locations are involved.

For example, the bundle approach was tested in an IHI Collaborative on perioperative safety, using the surgical site infection (SSI) prevention measures from the Surgical Care Improvement Project (SCIP). These measures cross multiple geographic areas — the preoperative holding area, the operating room, postanesthesia care, and the postoperative ward — and occur at different times in the perioperative process. There were often at least four different teams involved, one or more from each geographic area, who rarely came in contact with each other. Although teams were able to improve the individual elements of care that occurred in their respective areas, the bundle approach was less successful — that is, Collaborative participants found it difficult to develop strategies that applied to all team members toward achieving all-or-none compliance for SSI.

If a particular type of harm (e.g., sepsis) occurs in more than one location, develop a bundle for each location and design good handoffs. For example, there are two Sepsis Bundles — one for management of septic patients in the emergency department, and another for management of septic patients in the ICU.

The multidisciplinary care team develops the bundle.

Communication and teamwork are fundamental to the success of a bundle. Having bundles developed by care teams with members from many disciplines will improve the likelihood of the bundle's acceptance and success.

Bundle elements should be descriptive rather than prescriptive, to allow for local customization and appropriate clinical judgment.

As noted previously, it is essential that bundle elements have the consensus of local clinicians. In some cases, the science or generally accepted opinion may support a general care element, but the care element could be implemented in several ways or have varying interpretations. For example, the DVT and PUD prophylaxis elements of the Ventilator Bundle do not specify the *type* of prophylaxis. Local clinicians will determine the appropriate form for their patient population and care setting. Bundle elements must be applied sensibly; they should never be forced when clinically inappropriate, and there should always be an “opt out” choice. All exceptions should be documented in the patient record so that all members of the care team are aware of the rationale.

Compliance with bundles is measured using all-or-none measurement, with a goal of 95 percent or greater.

Compliance with bundles is measured by documentation of adherence to all elements of the bundle using a simple “yes” or “no.” If all elements have been accomplished, or if an element was documented as medically contraindicated (with the goal that all care team members know the rationale for exceptions, which may change over time), the bundle is counted as complete for that patient. If any of the elements are absent in the documentation, the bundle is incomplete (no “partial credit” is given).

Bundles are designed around specific elements of care received by a patient; thus the patient should be the denominator for each bundle element. We do *not* recommend including general processes that are not patient interventions (for example, hand hygiene or contact precautions, which are measured as compliance by observed opportunity of caregiver interaction; or room cleaning, which is measured daily), as this may lead to a mixed measure that is difficult to track. The percentage of all-or-none compliance for a bundle always focuses on a patient population (e.g., the percentage of patients on ventilators in the ICU who received all bundle elements, or had documentation of contraindications). This all-or-none measurement approach for bundles focuses attention on the importance of delivering all elements of the bundle to the patient, unless medically contraindicated.

Theory of Change: Why Do Bundles Produce Better Outcomes?

When teams design changes to care, those changes are extensions of a theory of how they will work to improve care. For implementation of bundles, the “theory of change” is essentially the answer to the question, “Why do bundles of care interventions, when systematically and reliably applied, produce better outcomes for patients?”

We found that using bundles and all-or-none measurement changes the way care is provided in important ways.

1. Bundles change the assumption that evidence-based care is being delivered reliably.

If each of five bundle elements is delivered at 90 percent reliability, then the bundle is delivered at 59 percent reliability, as bundle reliability is the product of each element’s reliability (90% x 90% x 90% x 90% x 90%). Typically, most clinicians assume that the bundle elements are being reliably performed on their patients. However, when they collect their initial data, they are often surprised at the low levels of all-or-none bundle compliance, with some ICUs finding reliability levels of 10 to 20 percent.

2. Bundles promote awareness that the entire care team must work together in a system designed for reliability.

Teams that have achieved high levels of bundle compliance and concomitant improved outcomes did so through working as a team in new ways. Contributors to bundle success include using specific daily goals developed by the team and patient, multidisciplinary rounds where the bundle elements are discussed and checked, and debriefs at the end of the day to reflect on compliance and to plan ongoing improvements.

3. Bundles promote the use of improvement methods to redesign care processes.

Organizations and the clinical teams within them are all different. How they learn to implement the bundle reliably is something that they must discover by systematically using an improvement method. Teams can use many methods to improve process reliability and outcomes. In the original bundle development work, teams used the Model for Improvement,⁵ which begins with three questions:

- *What are we trying to accomplish?*
The aim of using bundles is to reduce harm and improve care for the patient through improving the reliability of care processes.
- *How will we know the change is an improvement?*
Two measures will indicate if changes are leading to improvement: all-or-none bundle compliance and improved patient outcomes.
- *What changes can we make that will result in improvement?*
Several changes are listed above — daily goals, multidisciplinary rounds, and debriefing; in addition, effective changes include the use of huddles, checklists, standardization, and co-location of resources (e.g., the central line equipment cart).

Teams then test the changes using the Plan-Do-Study-Act (PDSA) cycle iteratively to learn and to refine the changes until they are able to produce reliable processes that lead to improved outcomes.

Evolution of Bundles Designed in IHI Initiatives

Central Line Bundle and Ventilator Bundle

The first bundles developed in IHI initiatives, the Central Line Bundle and the Ventilator Bundle, were used subsequently in IHI's critical care initiative in the IMPACT network starting in July 2002. After improving and sustaining performance with the Central Line and Ventilator Bundles, teams and faculty noticed that central line-associated bloodstream infection (CLABSI) and ventilator-associated pneumonia (VAP) rates in those intensive care units decreased dramatically. Data from 35 intensive care units in the IMPACT network showed that, with high Ventilator Bundle compliance (greater than 95 percent), VAP rates were reduced by 44.5 percent.⁶

In analyzing these improved outcomes, teams and faculty determined that it was more than just measuring these care elements as a bundle that led to success. The changes made to *how* work was done and *how* the team interacted contributed to the high levels of performance (greater than 95 percent compliance with the bundle). Examples of such changes included use of checklists, revising the structure and process of daily multidisciplinary rounds, and use of daily goal sheets. Both the Central Line Bundle and the Ventilator Bundle were included as key interventions in IHI's 100,000 Lives Campaign and 5 Million Lives Campaign. Over 4,000 US hospitals participated in the Campaigns between 2006 and 2008. Those hospitals were surveyed in 2007 about results following bundle implementation; 65 hospitals reported going one year or more without a VAP in an ICU setting, and 35 hospitals reported six months or more of no CLABSI in at least one intensive care unit.⁷

Hospitals have continued to use these two bundles with intensive care patients and report on their improved outcomes, which have repeatedly been linked to sustained compliance with the bundle. For the Ventilator Bundle, publications from the Mayo Clinic, Mercy & Unity Hospitals, and Boston Medical Center have reported significant decreases in VAP following implementation of the Ventilator Bundle and described the process and work design changes that were required for success.^{8,9,10} Others have made local modifications to this bundle, a worthwhile strategy within the aforementioned guidelines, and reported on their success as well.¹¹

Similar results have been published regarding the Central Line Bundle, with one study from the US Veterans Administration noting a significant reduction in CLABSI, as well as a strong correlation between compliance with the bundle and reduced CLABSI rates.¹² Two recently published studies reported on retrospective review of CLABSI, VAP, and compliance with the bundles from surveyed hospitals participating in the Centers for Disease Control and Prevention National Health Safety Network. Both studies found that only when Central Line Bundle and Ventilator Bundle compliance were sustained at 95 percent or higher were decreases in the associated infections (CLABSI and VAP respectively) observed; further, they found that both having a bundle policy and monitoring compliance were required to achieve reductions in infections.^{13,14}

Subsequent work in the Keystone ICU project has demonstrated that a multi-factorial approach, including adherence to the five evidence-based procedures in the Central Line Bundle, when combined with a daily goals sheet, team training and communication, a unit-based program to improve the safety culture, and other factors, can lead to dramatic, sustained reduction — up to 66 percent — in CLABSI rates.¹⁵

In England, the Patient Safety First Campaign (sponsored by the National Patient Safety Agency, the NHS Institute for Innovation and Improvement, and The Health Foundation) has also included the two bundles.¹⁶ The Scottish Patient Safety Programme, launched in 2007 in collaboration with IHI, included the Central Line Bundle and the Ventilator Bundle; one hospital in Scotland recently published significant reductions in VAP after implementing the Ventilator Bundle, a result that had not been achieved with earlier improvement initiatives.¹⁷

Severe Sepsis Bundles and Perinatal Care Bundles

The bundle concept has been applied in other clinical areas, including sepsis, which has also led to reported improvements in outcomes. Two Severe Sepsis Bundles — one on resuscitation¹⁸ and another on management¹⁹ — are a distillation of the concepts and recommendations found in the practice guidelines initially published by the Surviving Sepsis Campaign in 2004. Two publications have noted decreases in hospital mortality and length of stay associated with implementation of one or both Sepsis Bundles.^{20,21} A subsequent study also reported on mortality reductions and estimated that 47 lives were saved in the hospital's first year after implementation of the Severe Sepsis Bundles and a savings of over \$1 million for the hospital.²² Bundles, like all clinical work, need to change as the evidence to support them changes. With regard to the current Sepsis Bundles, the use of drotrecogin alpha has been eliminated as subsequent clinical trials found it ineffective.²³

Other bundles currently being tested within IHI initiatives include the Perinatal Elective Induction and Augmentation Bundles.²⁴ Hospitals and organizations in the US and UK have also been testing bundles related to peripheral intravenous catheters, catheter-associated urinary tract infections, and dementia; we look forward to reports on results from the use of these bundles.

Conclusion

The use of bundles of care interventions as an approach to improving the reliability of care received by patients and preventing certain serious clinical outcomes has been demonstrated successfully for nearly ten years, with a growing body of published results in medical journals.²⁵ The first two IHI bundles — the Central Line Bundle and the Ventilator Bundle — have been recognized by the National Quality Forum and placed on their list of endorsed patient safety measures.²⁶

Our initial hypothesis — that using a bundle approach can be an effective strategy for improving care — has been confirmed by an increasing body of evidence. Experience has also shown that while the bundle approach has worked well and been associated with improved outcomes in many cases, sometimes the bundle approach has not been a good fit for a clinical topic. Our learning about the reasons for bundle success or failure informs the guidelines for bundle development and implementation described in this paper.

Success is related to more than simply “doing a bundle.” Implementing a bundle with high reliability requires redesign of work processes, communication strategies, and infrastructure, along with sustained measurement and vigilance. Bundles are neither “magic bullets” nor comprehensive care for any condition or patient situation; rather, they are one strategy among many that hospitals must implement in order to prevent serious complications in their patients — and save lives.

IHI and other organizations will likely develop bundles in the future for clinical teams to improve the delivery of care by approaching care as a “bundle” with all-or-none measurement. It is important for future bundles to be tested since, in our experience, not all clinical topics lend themselves to this approach. Further, when the bundle approach works there is often a period of determining the exact definition of each bundle element. To ensure optimal support from clinicians, bundle developers should always remember to select elements that are supported by evidence. Finally, it is worth reiterating that a bundle itself does not improve care; rather, improvement is a result of the strategies taken by the team to redesign work, communicate better, and work more effectively toward achieving patient goals.

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