



IHI

Apuntes

Bundles y datos

The Seven Propositions of the Science of Improvement

<http://www.ihl.org/knowledge/Pages/Publications/SevenPropositionsScienceofImprovement.aspx>

Perla RJ, Provost LP, Parry GJ. The seven propositions of the science of improvement. *Quality Management in Health Care*. 2013;22(3):170-186.

A standard view of the science of improvement does not presently exist that is grounded in the philosophical and theoretical basis of the field. The seven propositions outlined in this article demonstrate the value of examining the underpinnings of improvement, which is necessary to both advance the field and minimize confusion about what the phrase “science of improvement” represents.

Context: The phrase “Science of Improvement” or “Improvement Science” is commonly used today by a range of people and professions to mean different things, creating confusion to those trying to learn about improvement. In this article, we briefly define the concepts of improvement and science, and review the history of the consideration of “improvement” as a science.

Methods: We trace key concepts and ideas in improvement to their philosophical and theoretical foundation with a focus on Deming's System of Profound Knowledge. We suggest that Deming's system has a firm association with many contemporary and historic philosophic and scientific debates and concepts. With reference to these debates and concepts, we identify 7 propositions that provide the scientific and philosophical foundation for the science of improvement.

Findings: A standard view of the science of improvement does not presently exist that is grounded in the philosophical and theoretical basis of the field. **The 7 propositions outlined here demonstrate the value of examining the underpinnings of improvement.** This is needed to both advance the field and minimize confusion about what the phrase “science of improvement” represents. We argue that advanced scientists of improvement are those who like Deming and Shewhart can

integrate ideas, concepts, and models between scientific disciplines for the purpose of developing more robust improvement models, tools, and techniques with a focus on application and problem solving in real world contexts.

Conclusions: The epistemological foundations and theoretical basis of the science of improvement and its reasoning methods need to be critically examined to ensure its continued development and relevance. If improvement efforts and projects in health care are to be characterized under the canon of science, then health care professionals engaged in quality improvement work would benefit from a standard set of core principles, a standard lexicon, and an understanding of the evolution of the science of improvement.

SEVEN PROPOSITIONS OF THE SCIENCE OF IMPROVEMENT

1. The science of improvement is grounded in testing and learning cycles.
2. The philosophical foundation of the science of improvement is conceptualistic pragmatism.
3. The science of improvement embraces a combination of psychology and logic (ie, a weak form of “psychologism”).
4. The science of improvement considers the contexts of justification *and* discovery.
5. The science of improvement requires the use of operational definitions.
6. The science of improvement employs Shewhart’s theory of cause systems.
7. Systems theory directly informs the science of improvement.

What Is a Bundle?

<http://www.ihl.org/knowledge/Pages/ImprovementStories/WhatIsaBundle.aspx>

IHI Vice President and patient safety expert, Carol Haraden, PhD, comments on the power and popularity of “bundles” in improvement initiatives. While the allure of this tool is undeniable, says Haraden, quality teams should resist the impulse to label any list of good changes a bundle. She clarifies what a bundle is and is not, and suggests tips for using bundles most effectively to get results.

Q: What is a bundle?

A: IHI developed the concept of “bundles” to help health care providers more reliably deliver the best possible care for patients undergoing particular treatments with inherent risks. A bundle is a structured way of improving the processes of care and patient outcomes: a small, straightforward set of evidence-based practices — generally three to five — that, when performed collectively and reliably, have been proven to improve patient outcomes.¹

Q: What makes a bundle so special?

A: The power of a bundle comes from the body of science behind it and the method of execution: with complete consistency. It’s not that the changes in a bundle are new; they’re well established best practices, but they’re often not performed uniformly, making treatment unreliable, at times idiosyncratic. A bundle ties the changes together into a package of interventions that people know must be followed for every patient, every single time.

Q: So a bundle is a list of the right things to do for a given patient?

¹ Resar R, Pronovost P, Haraden C, Simmonds T, et al. [Using a bundle approach to improve ventilator care processes and reduce ventilator-associated pneumonia](#). Joint Commission Journal on Quality and Patient Safety. 2005;31(5):243-248.

A: It resembles a list, but a bundle is more than that. A bundle has specific elements that make it unique.

- The changes are *all necessary and all sufficient*, so if you've got four changes in the bundle and you remove any one of them, you wouldn't get the same results — meaning: the patient won't have as high a chance of getting better. It's a cohesive unit of steps that must *all* be completed to succeed.
- The changes are all based on randomized controlled trials, what we call *Level 1 evidence*. They've been proven in scientific tests and are accepted, well-established. There should be no controversy involved, no debate or discussion of bundle elements. A bundle focuses on *how* to deliver the best care — not *what* the care should be. We want providers to get right to work on the how: on completing steps x, y, and z for every patient.
- The changes in a bundle are clear-cut and straightforward; they involve *all-or-nothing measurement*. Successfully completing each step is a simple and straightforward process. It's a "yes" or "no" answer: "Yes, I did this step and that one; no, I did not yet do this last one." Successfully implementing a bundle is clear-cut: "Yes, I completed the ENTIRE bundle, or no, I did not complete the ENTIRE bundle." There is no in between; no partial "credit" for doing some of the steps some of the time.
- Bundle changes also occur *in the same time and space continuum*: at a specific time and in a specific place, no matter what. This might be during morning rounds every day or every six hours at the patient's bedside, for instance.

Q: Can you give an example?

A: The [5 Million Lives Campaign](#) has several bundles as "planks" or interventions. This initiative is likely a big factor in the popularity of the bundle — thousands of people in hospitals across the country have learned about bundles by applying them as part of their participation in the Campaign. There are two bundles in the Campaign that have been incredibly effective helping hospitals reduce to nearly

zero the incidence of deadly infections that used to be so common they were accepted as unavoidable.

- [Central Line Bundle](#): This is a set of five steps to help prevent “catheter-related blood stream infections,” deadly bacterial infections that can be introduced through an IV in a patient’s vein supplying food, medications, blood or fluid. The steps are simple, common sense tasks: using proper hygiene and sterile contact barriers; properly cleaning the patient’s skin; finding the best vein possible for the IV; checking every day for infection; and removing or changing the line only when needed.
- [Ventilator Bundle](#): Ventilator-associated pneumonia (VAP) is a serious lung infection that can happen to patients on a ventilator. The Ventilator Bundle has four care steps: raising the head of the patient’s bed between 30 and 40 degrees; giving the patient medication to prevent stomach ulcers; preventing blood clots when patients are inactive; and seeing if patients can breathe on their own without a ventilator.

Q: What’s the problem with how people use bundles?

A: The concept of a bundle has such traction that people are trying to use them more often and in more ways than they really should. There’s a tendency to want to call *everything* a bundle, any checklist involving patient care procedures, for example. But a bundle isn’t a checklist, and just taking an ineffective checklist and calling it a bundle won’t make it any better. The goal is to make a process more reliable, and you do that by improving habits and processes. The magic of the bundle comes from the guidelines I’ve laid out here; the way the work is organized. People need to ask themselves: why will calling it a bundle make it better?

Q: What’s the difference between a bundle and a checklist?

A: A checklist can be very helpful and an important vehicle for ensuring safe and reliable care. The elements in a checklist are often a mixture of *nice-to-do* tasks or

processes (useful and important but not evidence-based changes) and *have-to-do* processes (proven by randomized control trials). A checklist may also have many, many elements.

A bundle is a small but critical set of processes all determined by Level 1 evidence. And it needs to meet all the criteria I described previously. Because some elements of a checklist are nice to do but not required, when they are not completed, there may be no effect on the patient. When a bundle element is missed, the patient is at much greater risk for serious complications.

There's also a level of accountability tied to a bundle that you don't always have with a checklist. An identified person or team owns it. A checklist might be owned by everybody on a floor or on a team, but we know that, in reality, when it's owned by everyone — *nobody* owns it! Things don't always get done. So maybe the pharmacist does one thing in a checklist, a nurse another, the doctor something else, but really it's no one person's job at the end of the day. A bundle is a person or a team's responsibility — period. And it's their job at a certain point and time — during rounds every single day, possibly. So it isn't the kind of thing where people say: "You check that, I'll check this." No. It's very clear who has to do what and when, within a specific time frame. The accountability and focus give a bundle a lot of its power.

Q: Can you give an example?

A: Let's take a discharge planning list. It's a reminder list of things people on a team should be doing throughout the patient's stay to help move the treatment process along toward discharge. People look at it often but no one typically "owns" it and there aren't clearly delineated dates and times attached to each element. It's so easy for incredibly busy nurses, aides, therapists, and doctors to assume that the next person will pick up where they left off.

Q: You're not saying don't bother with checklists, are you?

A: No, not at all. I don't mean to diminish the importance of a checklist. They can be really helpful; sometimes essential. When you get on a plane, you should be grateful to know that the pilot won't take off until going through every single task in the "pre-flight checklist." It's an incredibly important list; in fact, when you talk to a pilot, they don't call it a "checklist," they call it "pre-flight procedures." It's practically written in stone — revered and followed religiously with every flight. It's more than a list: it's a codified set of procedures.

Q: Is that the only problem with how bundles are used?

A: We're also seeing a trend where people keep adding changes to an existing bundle, a valid bundle they've adopted. It gets bigger and bigger — ultimately to the point where it's unworkable, impossible to follow and not effective anymore. If you do add changes to a bundle, the chance of success is much higher if you use the bundle criteria I've described here as a check for the appropriateness of inclusion.

Q: So, your final message about bundles is what?

A: A bundle is a specific tool with clear parameters. It has a small number of elements that are all scientifically robust, that when taken together create much improved outcomes. Don't feel compelled to convert helpful checklists into overloaded bundles. If the concept of a bundle becomes so broad and loose in meaning, its power will start to diminish. We don't want that to happen.

Using Care Bundles to Improve Health Care Quality

<http://www.ihl.org/knowledge/Pages/IHIWhitePapers/UsingCareBundles.aspx>

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.

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Innovation Series 2012

Executive Summary

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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.

Bundles 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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Implement the IHI Central Line Bundle

<http://www.ihl.org/knowledge/Pages/Changes/ImplementtheCentralLineBundle.aspx>

Central venous catheters (CVCs) are being increasingly used in the inpatient and outpatient settings to provide long-term venous access. CVCs disrupt the integrity of the skin, making infection with bacteria and/or fungi possible. Infection may spread to the bloodstream (bacteremia) and hemodynamic changes and organ dysfunction (severe sepsis) may ensue possibly leading to death. Approximately 90 percent of the catheter-related bloodstream infections (BSIs) occur with CVCs. [1]

Forty-eight percent of ICU patients have central venous catheters, accounting for 15 million central venous catheter-days per year in ICUs. Studies of catheter-related bloodstream infections that control for the underlying severity of illness suggest that attributable mortality for these infections is between 4 and 20 percent. Thus, it is estimated that between 500 and 4,000 US patients die annually due to bloodstream infections. [2]

In addition, nosocomial bloodstream infections prolong hospitalization by a mean of 7 days. Estimates of attributable cost per bloodstream infection are estimated to be between \$3,700 to \$29,000. [3]

Care bundles, in general, are groupings of best practices with respect to a disease process that individually improve care, but when applied together result in substantially greater improvement. The science supporting the bundle components is sufficiently established to be considered standard of care.

The IHI Central Line Bundle is a group of evidence-based interventions for patients with intravascular central catheters that, when implemented together, result in better outcomes than when implemented individually.

The key components of the IHI Central Line Bundle are:

- Hand Hygiene
- Maximal Barrier Precautions Upon Insertion
- Chlorhexidine Skin Antisepsis
- Optimal Catheter Site Selection, with Avoidance of the Femoral Vein for Central Venous Access in Adult Patients
- Daily Review of Line Necessity with Prompt Removal of Unnecessary Lines

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IHI Central Line Bundle: Hand Hygiene

Hand hygiene is an integral part of the IHI Central Line Bundle and has been correlated with reduction in the rate of central line infection. One way to decrease the likelihood of central line infections is to use proper hand hygiene. Washing hands or using an alcohol-based waterless hand cleaner can help to prevent contamination of central line sites and bloodstream infections. [O'Grady NP, Alexander M, Dellinger EP, et al. Guidelines for the prevention of intravascular catheter-related infections. Centers for Disease Control and Prevention. *MMWR*

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Some appropriate times for handwashing include:

- When they are obviously soiled
- Before and after invasive procedures
- Between patients
- After removing gloves
- Before eating
- After using the bathroom
- If contamination is suspected

Tips

- Empower nursing to enforce use of a central line checklist to be sure all processes related to central line placement are executed for each line placement.
- Include hand hygiene as part of your checklist for central line placement.
- Keep soap/alcohol-based handwashing dispensers prominently placed and make universal precautions equipment, such as gloves, only available near hand sanitation equipment.
- Post signs at the entry and exits to the patient room as reminders.
- Initiate a campaign using posters including photos of celebrated hospital doctors/employees recommending handwashing.
- Create an environment where reminding each other about handwashing is encouraged.
- Signs often become "invisible" after just a few days. Try to alter them weekly or monthly (color, shape size). *[Submitted by Cynthia Valentine]*

IHI Central Line Bundle: Maximal Barrier Precautions Upon Insertion

One way to decrease the likelihood of central line infections is to apply maximal barrier precautions in preparation for line insertion. This is an integral part of the IHI Central Line Bundle and has been correlated with reduction in the rate of central line infection.

For the operator placing the central line and for those assisting in the procedure, maximal barrier precautions means strict compliance with handwashing, wearing a cap, mask, sterile gown and gloves. The cap should cover all hair and the mask should cover the nose and mouth tightly. These precautions are the same as for any other surgical procedure that carries a risk of infection.

For the patient, maximal barrier precautions means covering the patient from head to toe with a sterile drape with a small opening for the site of insertion.

Maximal barrier precautions clearly decrease the odds of developing catheter-related bloodstream infections. Two studies show that the odds of developing a central line infection were higher if maximal barrier precautions were not used. For pulmonary artery catheters, the odds ratio of developing infection were more than two times greater for placement without maximal barrier precautions.[1] A study of similar design found that this rate was six times higher for placement of central line catheters.[2]

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238.

Tips

- Empower nursing to enforce use of a central line checklist to be sure all processes related to central line placement are executed for each line placement.
- Include maximal barrier precautions as part of your checklist for central line placement.
- Keep equipment ready stocked in a cart for central line placement to avoid the difficulty of finding necessary equipment to institute maximal barrier precautions.

IHI Central Line Bundle: Chlorhexidine Skin Antisepsis

Chlorhexidine skin antisepsis has been proven to provide better skin antisepsis than other antiseptic agents such as povidone-iodine solutions. This is an integral part of the IHI Central Line Bundle and has been correlated with reduction in the rate of central line infection.

The technique, for most kits, is as follows:

- Prepare skin with antiseptic/detergent chlorhexidine 2 percent in 70 percent isopropyl alcohol.
- Pinch wings on the chlorhexidine applicator to break open the ampule. Hold the applicator down to allow the solution to saturate the pad.
- Press sponge against skin, apply chlorhexidine solution using a back and forth friction scrub for at least 30 seconds. Do not wipe or blot.
- Allow antiseptic solution time to *dry completely* before puncturing the site (~ 2 minutes).

Tips

- Empower nursing to enforce use of a central line checklist to be sure all processes related to central line placement are executed for each line placement.
- Include chlorhexadine antiseptics as part of your checklist for central line placement.
- Include chlorhexadine antiseptics kits in carts storing central line equipment. Many central line kits include povidone-iodine kits and these must be avoided.
- Ensure that solution dries completely before an attempted line insertion.

IHI Central Line Bundle: Optimal Catheter Site Selection, with Avoidance of the Femoral Vein for Central Venous Access in Adult Patients

This is an integral part of the IHI Central Line Bundle and has been correlated with reduction in the rate of central line infection.

Percutaneously inserted catheters are the most commonly used central catheters. In a prospective observational study assessing catheters placed by a critical care medicine department in a university teaching hospital, the site of insertion did not alter the risk of infection. The authors concluded that the site of insertion was not a risk factor for infection when experienced physicians insert the catheters, strict sterile technique is used, and trained intensive care unit nursing staff perform catheter care.[1]

Other studies have shown that in less controlled environments, the site of insertion is a risk factor for infection. Mermel and colleagues were able to demonstrate that the great majority of infections develop at the insertion site. Another risk factor was

use of the jugular insertion site over the subclavian site.[2] In addition, for use of total parenteral nutrition, McCarthy demonstrated a similar effect.[3]

Several non-randomized studies show that the subclavian vein site is associated with a lower risk of central line-associated bloodstream infection than the internal jugular vein, but the risk and benefit of infectious and non-infectious complications must be considered on an individual basis when determining which insertion site to use. The femoral site is associated with greater risk of infection in adults, however may be limited to overweight adult patients.[4-8]

Given that teams undertaking this initiative may not yet have the processes in place to duplicate the conditions found in the Deshpande study, whenever possible the femoral site should be avoided and the subclavian line site should be preferred over the jugular and femoral sites for non-tunneled catheters in adult patients. This recommendation is based solely on the likelihood of reducing infectious complications. Subclavian placement may have other associated risks. The IHI Central Line Bundle requirement for optimal site selection suggests that other factors (e.g., the potential for mechanical complications, the risk of subclavian vein stenosis, and catheter-operator skill) should be considered when deciding where to place the catheter. In these instances, teams are considered compliant with the bundle element as long as they use a rationale construct to choose the site.

The core aspect of site selection is the risk/benefit analysis by a physician as to whether the subclavian vein is most appropriate for the patient. There will be occasions when the physician determines that the risks and benefits of using the subclavian vein outweigh the benefits, and a different vessel is selected. For the purposes of bundle compliance, if there is dialogue among the clinical team members as to the selection site and rationale, and there is documentation as to the reasons for selecting a specific different vessel, this aspect of the bundle should be considered as in compliance. It is not the intent of the bundle to force a physician to take an action that he or she feels is not clinically appropriate.

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Tips

- Empower nursing to enforce use of a central line checklist to be sure all

processes related to central line placement are executed for each line placement.

- Include optimal site selection as part of your checklist for central line placement with room for appropriate contraindications (e.g., bleeding risks).

IHI Central Line Bundle: Daily Review of Line Necessity with Prompt Removal of Unnecessary Lines

This is an integral part of the IHI Central Line Bundle and has been correlated with reduction in the rate of central line infection.

Daily review of central line necessity will prevent unnecessary delays in removing lines that are no longer clearly necessary in the care of the patient. Many times, central lines remain in place simply because of their reliable access and because personnel have not considered removing the line. However, it is clear that the risk of infection increases over time as the line remains in place and that the risk of infection is decreased if removed.

Tips

- Empower nursing to enforce use of a central line checklist to be sure all processes related to central line placement are executed for each line placement.
- Include daily review of line necessity as part of your multidisciplinary rounds.
- Include assessment for removal of central lines as part of your daily goal sheets.
- Record time and date of line placement for record keeping purposes and evaluation by staff to aid in decision making.

Central Line Insertion Checklist

Virginia Mason Medical Center. Seattle, Washington, USA

Implementing a central line checklist at the time of insertion will help to ensure that all processes related to central line placement are executed for *each* line placement, thereby leading to a reliable process. Nurses should be empowered to supervise the preparations using the checklist prior to line insertion and to stop the process if necessary. This checklist includes a list of activities that are considered standard work before, during, and after the procedure, as well as a safety checklist.

*NOTE: The checklist is particularly effective if used in conjunction with the [Daily Goals Worksheet](#) that can be completed during daily rounds on the patient.

Central Line Procedural Checklist

Indication: To document procedural practices in the CCU related to insertion technique for: CVP lines, dialysis access ports, and central lines (including PICC).

Type of catheter:	<input type="checkbox"/> Central Line	Location: _____
	<input type="checkbox"/> CVP	Location: _____
	<input type="checkbox"/> Dialysis Catheter	Location: _____
	<input type="checkbox"/> PICC Line	Location: _____
Is this a NEW line:	<input type="checkbox"/> YES	<input type="checkbox"/> NO
Is the procedure:	<input type="checkbox"/> Elective	<input type="checkbox"/> Emergent
	<input type="checkbox"/> Re-wire	<input type="checkbox"/> Re-position
		<input type="checkbox"/> _____

Procedural Checklist		
Safety Practice	YES	YES (After Reminder)
Before procedure, did the provider:		
➤ PERFORM PROCEDURAL PAUSE		
Perform patient ID X 2	<input type="checkbox"/>	<input type="checkbox"/>
Announce the procedure to be performed	<input type="checkbox"/>	<input type="checkbox"/>
Mark / assess site	<input type="checkbox"/>	<input type="checkbox"/>
Position patient correctly for procedure	<input type="checkbox"/>	<input type="checkbox"/>
Assemble equipment / verify supplies	<input type="checkbox"/>	<input type="checkbox"/>
Utilize relevant documents (chart / forms)	<input type="checkbox"/>	<input type="checkbox"/>
Order follow-up Radiology images (PRN)	<input type="checkbox"/>	<input type="checkbox"/>
➤ Cleanse hands? (ASK, if unsure)	<input type="checkbox"/>	<input type="checkbox"/>
➤ Prep procedure site with ChloroPrep?		
*30 seconds for dry site	<input type="checkbox"/>	<input type="checkbox"/>
**2 minutes for moist site (esp. femoral)		
➤ Use large drape to cover patient in sterile fashion?	<input type="checkbox"/>	<input type="checkbox"/>
During procedure, did the provider:		
➤ Wear sterile gloves during catheter insertion?	<input type="checkbox"/>	<input type="checkbox"/>
➤ Wear hat, mask, and sterile gown?	<input type="checkbox"/>	<input type="checkbox"/>
➤ Maintain sterile field?	<input type="checkbox"/>	<input type="checkbox"/>
➤ Use ultrasound/Sonasite if appropriate?	<input type="checkbox"/>	<input type="checkbox"/>
➤ Did assisting physician follow the same precautions? (hand washing, mask, gloves, gown)	<input type="checkbox"/>	<input type="checkbox"/>
➤ Did all staff and patient in the room wear a mask?	<input type="checkbox"/>	<input type="checkbox"/>
After the procedure:		
➤ Was sterile technique maintained when applying dressing?		
➤ Was dressing dated?		

Name of Intensivist: _____

Name of Procedure MD _____

Name of Assisting MD _____

Name of RN (auditor): _____ Today's Date: ____ - ____ - ____

Room: CCU Bed # _____

PLEASE RETURN COMPLETED FORM TO:
"BSI FORMS" LABELED ENVELOPE IN CCU-7 CONFERENCE ROOM

Measure Information Form:

Central Line Bundle Compliance

Intervention(s): Prevention of Central Line-Associated Primary Bloodstream Infections

Definition: The percentage of intensive care patients in the included ICUs with central lines for whom all five elements of the central line “bundle” are documented on the daily goals sheet, central line checklist, patient’s medical record, or other documentation tool.

Goal: 95% of all patients with central lines in the included intensive care units receive all five elements of the central line bundle. Historically, this level of reliability has been achieved by building an infrastructure using central line insertion check lists, multidisciplinary rounds, and daily goals.

Matches Existing Measures: None.

CALCULATION DETAILS:

Numerator Definition: Number of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place. The central line bundle elements include:

- Hand hygiene
- Maximal barrier precautions upon insertion
- Chlorhexidine skin antisepsis
- Optimal Catheter Site Selection, with Avoidance of the Femoral Vein for Central Venous Access in Adult Patients
- Daily review of line necessity with prompt removal of unnecessary lines

NOTE: This is an “all or nothing” indicator. If any of the elements are not documented, do not count the patient in the numerator. If a bundle element is contraindicated for a particular patient and this is documented appropriately on the checklist, then the bundle can still be considered compliant with regards to that

element.

Numerator Exclusions: Same as denominator exclusions

Denominator Definition: Total number of intensive care patients with central lines on day of week of sample

Denominator Exclusions:

- Patients outside the intensive care unit and patients whose lines were not placed in the intensive care unit
- Patients less than 18 years of age at the date of ICU admission

Measurement Period: Monthly

Definition of Terms:

- **Central Line Bundle:** A group of interventions related to patients with intravascular central catheters that, when implemented together, result in better outcomes than when implemented individually. When implemented with a higher level of reliability, basic structural changes are required on unit to maintain compliance.
- **Central Line:** A vascular access device that terminates at or close to the heart or one of the great vessels. An umbilical artery or vein catheter is considered a central line. **Note: Neither the location of the insertion site nor the type of device may be used solely to determine whether the line qualifies as a “central” line. Only if the location of the tip of the line meets the criteria above does the device qualify as a central line. (JCAHO)**
- **Great Vessels:** Aorta, superior vena and inferior vena cava, brachiocephalic veins, internal jugular veins, and subclavian veins (JCAHO)
- **Hand Hygiene:** Recommendations about hand hygiene are found in the CDC guidelines www.cdc.gov/mmwr/PDF/rr/rr5110.pdf
 - When caring for central venous catheters, wash hands or use an alcohol-based waterless hand cleaner:
 - Before and after palpating catheter insertion sites

- Before and after inserting, replacing, accessing, repairing, or dressing and intravascular catheter
- Palpation of the insertion site should not be performed after the application of antiseptic, unless aseptic technique is maintained.
- Wash hands if hands are obviously soiled or if contamination is suspected.
- Wash hands or use an alcohol-based waterless hand cleaner between patients, after removing gloves and after using the bathroom.
- **Maximal barrier precautions on insertion: Include all of the following:**
 - For the Provider: Hand hygiene, non-sterile cap and mask, all hair under cap, mask covering nose and mouth tightly, and sterile gown and gloves
 - For the Patient: Cover patient's head and body with a large sterile drape
- **Chlorhexidine skin antisepsis: Includes all of the following:**
 - Prepare skin with antiseptic/detergent chlorhexidine 2% in 70% isopropyl alcohol by saturating the pad, pressing it against the skin, and applying chlorhexidine solution using a back-and-forth friction scrub for at least 30 seconds. Do not wipe or blot.
 - Allow antiseptic solution time to dry completely before puncturing the site (~ 2 minutes).
- **Optimal catheter site selection:** The femoral site is associated with greater risk of infection in adults and should be avoided. The subclavian line site may be preferred over the jugular site for non-tunneled catheters in adult patients. This recommendation is based solely on the likelihood of reducing infectious complications. For the purposes of bundle compliance, if there is dialogue among the clinical team members as to the selection site and rationale, and there is documentation as to the reasons for selecting a specific vessel, this aspect of the bundle should be considered as in compliance.
- **Daily review for necessity and prompt removal of unnecessary lines:**

- The ICU patient with a central line will be reviewed daily, with a notation on the daily goals sheet or medical record indicating the continued need for the central line. Routine replacement should be avoided, and all lines should be removed as early as possible.

Calculate as: Number of intensive care patients with central lines for whom all elements of the central line bundle are documented and in place / Total number of intensive care patients with central lines on day of week of sample [x 100 to express as a percentage]

Comments: This measure is an assessment of how well the team is adhering to the central line bundle. IHI's experience has been that teams begin to demonstrate improvement in outcomes when they get the process right more frequently. Therefore, it is important to measure the compliance with the entire central line bundle, not just parts of the bundle. Incorporating the five elements of the central line bundle into a central line insertion checklist and a daily goals form, and reviewing lines daily during multidisciplinary rounds, allows for easy review of bundle compliance during weekly survey. This also serves as a reminder during rounds to increase compliance with the bundle elements.

COLLECTION STRATEGY:

Use a central line insertion checklist, daily goal sheet, medical record, or other documentation tool as data sources. Review for implementation of the central line bundle.

The sample should include all patients with central lines in the intensive care unit. Only patients with all five aspects of central line bundle in place are recorded as being in compliance with the central line bundle.

Sampling Plan: Conduct the sample one day per week. This is a weekly compliance measure. Rotate the days of the week and the shifts. On the day of the sample, the medical records (including daily goals sheets and central line checklists) are examined for evidence of bundle compliance in all patients in the ICU for whom central lines were placed in the ICU. The central line checklist should be used to

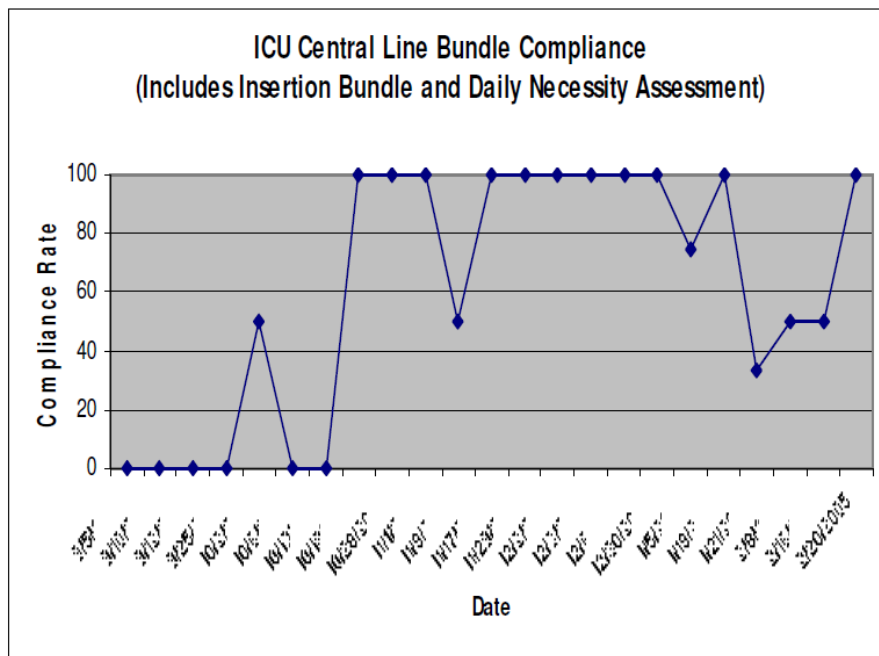
confirm compliance with the elements that are specific to the time of initial insertion and the daily goals sheet can be used to confirm compliance for that day with the element of “daily review of line necessity with prompt removal of unnecessary lines.” A patient who remains in the ICU with a central line for more than one week will be included in more than one weekly compliance measure, although the compliance with the initial insertion bundle elements will remain the same.

If even one element is missing, the case is not in compliance with the bundle. For example, if there are 7 patients with central lines, and 6 have all 5 bundle elements completed, then 6/7 (86%) is the rate of compliance with the central line bundle. If all 7 had all 5 elements completed, compliance would be 100%. If all seven were missing even a single item, compliance would be 0%. This measure is always expressed as a percentage.

SAMPLE GRAPH:

Our Lady of Lourdes, Binghamton, NY

(began work with central line bundle in March, 2004)



Measure Information Form:**Central Line-Associated Primary Bloodstream Infection (BSI) Rate per
1000 Central Line-Days****Intervention(s):** Prevention of Central Line-Associated Primary Bloodstream Infection**Definition:** The number of central line catheter-related bloodstream infections per 1000 central line days is the standard measure for surveillance by the CDC and JCAHO. (The specific surveillance criteria are outlined in the CDC Guideline - *MMWR* Aug. 9,2002/51(RR 10) and JCAHO core measures.)**Goal:** The rate of CR-BSI will decrease by 50% in one year using the central line bundle. Once a hospital has gone more than 60 days between central line catheter-related bloodstream infections, the goal is for 150 or more days between central line infections.**Matches Existing Measures:**

- JCAHO ICU-4
- CDC guidelines

CALCULATION DETAILS:**Numerator Definition:** Number of central line-associated primary bloodstream infections (BSIs), in ICU patients with a laboratory confirmed BSI who had central line in place within the 48-hour period before the development of the BSI, by unit of attribution**Numerator Exclusions:** Secondary bloodstream infections, BSI present or incubating on admission to the ICU, clinical sepsis**Denominator Definition:** Number of central line-days, for patients who have a central line

in place and are receiving care in intensive care units, by type of unit

Denominator Exclusions :

- Patients in non-ICU areas
- Patients who do not have central lines in place while in the ICU
- Patients less than 18 years of age at the date of ICU admission

Measurement Period Length: Monthly

Definition of Terms:

- **Primary Catheter-Associated BSI** (from Appendix A of CDC Guideline MMWR Aug. 9, 2002/51(RR 10); 27-28 and the JCAHO Core Measures v06 – 10/2008 Glossary): The major site of infection is a bloodstream infection and the specific site is either laboratory confirmed BSI or clinical sepsis. For example, a patient with leukemia with a vascular catheter has two positive blood cultures with coagulase-negative staphylococci. Even if there are clinical signs and symptoms of localized infection at the vascular access site, but no other infection can be found, the infection is considered a primary bloodstream infection. Also, when a vascular access device is present and no other infection site is evident, then the BSI is considered a primary BSI regardless of whether there are localized signs of infection at the vascular access site (JCAHO). BSI is considered to be associated with a central line if the line was in use during the 48-hour period before development of the BSI.

If the time interval between onset of infection and device use is >48 hours, there should be compelling evidence that the infection is related to the central line (CDC).

- **Central Line:** A vascular access device that terminates at or close to the heart or one of the great vessels. An umbilical artery or vein catheter is considered a central line. **Note:** Neither the location of the insertion site nor the type of device may be used solely to determine whether the line qualifies as a “central” line. Only if the location of the tip of the line meets the criteria above does the device qualify as a central line. (CDC

http://www.cdc.gov/ncidod/dhqp/pdf/nhsn/NHSN_Manual_PatientSafetyProtocol_CURRENT.pdf and JCAHO)

- **Central Line Day:** Any day that a patient has a central line in place at the time the count is made. A patient with multiple central lines in a particular day should be counted as having only one central line day. Central line days should be counted in a consistent manner (e.g., at the same time each day). Central line days as the denominator include the total number of days of exposure to central venous catheters by all patients in the selected population during the selected time period. (JCAHO)
- **Great Vessels:** The National Nosocomial Infections Surveillance System (NNIS) at CDC was completed at the end of 2004 and is transitioning to the National Healthcare Safety Network (NHSN). With this transition, the definition of "great vessels" was changed effective January 1, 2005, to include the common femoral veins. The great vessels are now defined as including the aorta, pulmonary artery, superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, external iliac veins, and common femoral veins. (CDC http://www.cdc.gov/ncidod/dhqp/pdf/nhsn/NHSN_Manual_PatientSafetyProtocol_CURRENT.pdf)
- **Laboratory-Confirmed BSI:** Must meet at least one of the following criteria:
 - Criterion 1: Patient has a recognized pathogen cultured from one or more blood cultures, and the pathogen cultured from the blood is not related to an infection at another site.
 - Criterion 2: Patient has at least one of the following signs or symptoms: fever (100.4 [38C]), chills, or hypotension, and signs and symptoms and positive laboratory results are not related to an infection at another site, and at least one of the following:
 - Common skin contaminant [e.g., *Corynebacterium* sp. (formerly diphtheroids), *Bacillus* sp., *Propionibacterium* sp., coagulase-negative staphylococci, or micrococci] cultured from two or more blood cultures drawn on separate occasions.
 - Common skin contaminant [e.g. *Corynebacterium* sp. (formerly diphtheroids), *Bacillus* sp., *Propionibacterium* sp., coagulase-negative staphylococci, or

micrococci] is cultured from at least one blood culture from a patient with an intravascular line, and the physician institutes appropriate antimicrobial therapy.

- Positive antigen test on blood (e.g., *H. influenzae*, *S. pneumoniae*, *N. meningitidis*, or Group B streptococcus).

- **Secondary BSI:** A culture-confirmed bloodstream infection related to infection at another site. For example, a patient has pneumonia with *Pseudomonas aeruginosa* and grows the same pathogen in his blood cultures.

The pneumonia is considered the primary infection site and the BSI is secondary to it. Another example is a leukemic patient who appears septic and the blood cultures grow *E. coli*. The patient has a vascular catheter and also has signs and symptoms of a urinary tract infection, but no urine culture is ordered. The patient's primary infection is a symptomatic UTI complicated by a secondary bloodstream infection. Secondary BSIs are not included in this measure (JCAHO).

Calculate as: Number of central line-associated bloodstream infections / Number of central line-days [x 1,000]

Comments: See CDC guidelines and JCAHO Core Measure ICU-4 for more specific information.

COLLECTION STRATEGY:

Data Collection Approach: Report the monthly CR-BSI rate for the last several months (preferably the last three to six months). This will serve as your baseline. Continue to track the measure monthly. If possible, track the rate in an annotated run chart, with notes reflecting any interventions you made to improve.

If starting the work in one intensive care unit, track the rate for that unit alone, in order to see the improvement easily.

If your organization's infection control practitioner reports data quarterly, we recommend that you disaggregate the data and track by month. It is recommended that both the

numerator and denominator data elements be collected concurrently.

Data Accuracy: Data accuracy is enhanced when all definitions are used without modification and denominator data are collected in a consistent manner (e.g., at the same time each day). It is recommended that an infection control practitioner (ICP) collect the data for this measure, as some interpretation will be required. The patient is followed for evidence of infection for 48 hours after the removal of the central line, whether in the ICU or discharged from the ICU.

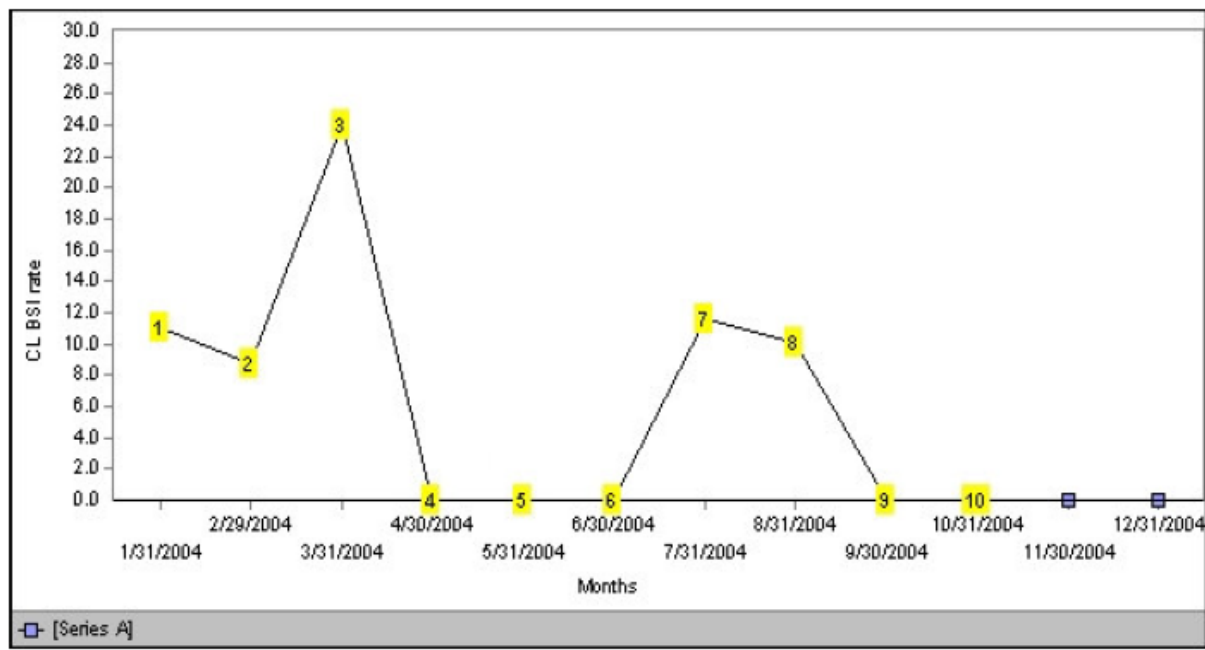
Hospitals may wish to implement periodic audits to monitor and ensure data accuracy.

Sampling: No sampling option available for this measure.

SAMPLE GRAPH:

Our Lady of Lourdes, Binghamton, NY

(CL BSI Rate shown is rate per 1000 line days)



Implement the IHI Ventilator Bundle

<http://www.ihl.org/knowledge/Pages/Changes/ImplementtheVentilatorBundle.aspx>

By definition, ventilator-associated pneumonia (VAP) is an airways infection that must have developed more than 48 hours after the patient was intubated. Preventing pneumonia of any variety seems at first blush to be a laudable goal. However, there are some reasons to be particularly concerned about the impact of pneumonia associated with ventilator use.

VAP is the leading cause of death amongst hospital-acquired infections, exceeding the rate of death due to central line infections, severe sepsis, and respiratory tract infections in the non-intubated patient. Perhaps the most concerning aspect of VAP is the high associated mortality. Hospital mortality of ventilated patients who develop VAP is 46 percent compared to 32 percent for ventilated patients who do not develop VAP. [1]

In addition, VAP prolongs time spent on the ventilator, length of ICU stay, and length of hospital stay after discharge from the ICU. [2] Strikingly, VAP adds an estimated cost of \$40,000 to a typical hospital admission. [3]

Reducing mortality due to ventilator-associated pneumonia requires an organized process that guarantees early recognition of pneumonia and consistent application of the best evidence-based practices.

The IHI Ventilator Bundle is a series of interventions related to ventilator care that, when implemented together, will achieve significantly better outcomes than when implemented individually.

The key components of the IHI Ventilator Bundle are:

- Elevation of the Head of the Bed
- Daily "Sedation Vacations" and Assessment of Readiness to Extubate

- Peptic Ulcer Disease Prophylaxis
- Deep Venous Thrombosis Prophylaxis
- Daily Oral Care with Chlorhexidine

References:

1. Ibrahim EH, Tracy L, Hill C, et al. The occurrence of ventilator-associated pneumonia in a community hospital: Risk factors and clinical outcomes. *Chest*. 2001 Aug;120(2):555-561.
2. Rello J, Ollendorf DA, Oster G, et al. VAP Outcomes Scientific Advisory Group. Epidemiology and outcomes of ventilator-associated pneumonia in a large US database. *Chest*. 2002 Dec;122(6):2115-2121.
3. Tablan OC, Anderson LJ, Besser R, et al. CDC Healthcare Infection Control Practices Advisory Committee. Guidelines for preventing health care-associated pneumonia, 2003: Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. *MMWR Recomm Rep*. 2004 Mar 26;53(RR-3):1-36.

IHI Ventilator Bundle: Elevation of the Head of the Bed

Elevation of the head of the bed is an integral part of the [IHI Ventilator Bundle](#) and has been correlated with reduction in the rate of ventilator-associated pneumonia. The recommended elevation is 30 to 45 degrees.

Drakulovic et al. conducted a randomized controlled trial in 86 mechanically ventilated patients assigned to semi-recumbent or supine body position. The trial demonstrated that suspected cases of ventilator-associated pneumonia had an incidence of 34 percent while in the semi-recumbent position suspected cases had an

incidence of 8 percent ($p=0.003$). Similarly, confirmed cases were 23 percent and 5 percent respectively ($p=0.018$). [1]

While it is not immediately clear whether the intervention aids in the prevention of ventilator-associated pneumonia by decreasing the risk of aspiration of gastrointestinal contents or oropharyngeal and nasopharyngeal secretions, this was the ostensible reason for the initial recommendation.

Another reason that the intervention was suggested was to improve patients' ventilation. For example, patients in the supine position will have lower spontaneous tidal volumes on pressure support ventilation than those seated in an upright position. Although patients may be on mandatory modes of ventilation, the improvement in position may aid ventilatory efforts and minimize atelectasis.

Some concerns with regard to this position have included patients sliding down in bed and, if skin integrity is compromised, shearing of skin. Others have commented on the possibility of patient discomfort. Although it is difficult to assess for these concerns in a controlled manner, anecdotal experience is that neither care providers nor patients (when off the ventilator and able to speak) have had this complaint.

References:

1. Drakulovic MB, Torres A, Bauer TT, Nicolas JM, Nogue S, Ferrer M. Supine body position as a risk factor for nosocomial pneumonia in mechanically ventilated patients: A randomised trial. *Lancet*. Nov 27 1999;354(9193):1851-1858.

Tips

- Implement a mechanism to ensure head-of-the-bed elevation, such as including this intervention on nursing flow sheets and as a topic at multidisciplinary rounds.
- Create an environment where respiratory therapists work collaboratively with nursing to maintain head-of-the-bed elevation.
- Involve families in the process by educating them about the importance of head-of-the-bed elevation and encourage them to notify clinical personnel

when the bed does not appear to be in the proper position.

- Use visual cues so it is easy to identify when the bed is in the proper position, such as a line on the wall that can only be seen if the bed is below a 30-degree angle.
- Include this intervention on order sets for initiation and weaning of mechanical ventilation, delivery of tube feedings, and provision of oral care.
- Post compliance with the intervention in a prominent place in your ICU to encourage change and motivate staff

IHI Ventilator Bundle: Daily "Sedation Vacations" and Assessment of Readiness to Extubate

Using daily "sedation vacations" and assessing the patient's readiness to extubate is an integral part of the [IHI Ventilator Bundle](#) and has been correlated with reduction in the rate of ventilator-acquired pneumonia.

Kress et al. conducted a randomized controlled trial in 128 adult patients on mechanical ventilation, randomized to daily interruption of sedation irrespective of clinical state or interruption at the clinician's discretion. Daily interruption resulted in a marked and highly significant reduction in time on mechanical ventilation. The duration of mechanical ventilation decreased from 7.3 days to 4.9 days ($p=0.004$). [1] It appears that lightening sedation decreases the amount of time spent on mechanical ventilation and therefore the risk of ventilator-acquired pneumonia. In addition, weaning patients from ventilators becomes easier when patients are able to assist themselves at extubation with coughing and control of secretions.

Sedation vacations are not without risks, however. Patients who are not sedated as deeply will have an increased potential for self-extubation. Therefore, the maneuver must be conducted in a careful fashion. In addition, there may be an increased potential for pain and anxiety associated with lightening sedation. Lastly, increased tone and poor synchrony with the ventilator during the maneuver may risk episodes of desaturation.

References:

1. Kress JP, Pohlman AS, O'Connor MF, Hall JB. Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. *New England Journal of Medicine*. May 18 2000;342(20):1471-1477.

Tips

- Implement a protocol to lighten sedation daily at an appropriate time to assess for neurological readiness to extubate. Include precautions to prevent self-extubation such as increased monitoring and vigilance during the trial.
- Include a sedation vacation strategy in your overall plan to wean the patient from the ventilator; if you have a weaning protocol, add "sedation vacation" to that strategy.
- Assess that compliance is occurring each day on multidisciplinary rounds.
- Consider implementation of a sedation scale such as the Riker scale to avoid oversedation.
- Post compliance with the intervention in a prominent place in your ICU to encourage change and motivate staff.

IHI Ventilator Bundle: Peptic Ulcer Disease Prophylaxis

Peptic ulcer disease prophylaxis is an integral part of the [IHI Ventilator Bundle](#) and has been correlated with reduction in the rate of ventilator-acquired pneumonia. Stress ulcerations are the most common cause of gastrointestinal bleeding in intensive care unit patients, and the presence of gastrointestinal bleeding due to these lesions is associated with a five-fold increase in mortality compared to ICU patients without bleeding. Applying peptic ulcer disease prophylaxis is therefore a necessary intervention in critically ill patients. A concern about prophylactic therapy for stress ulceration has been the potential for increased risk of nosocomial pneumonia. Agents that raise gastric pH may promote the growth of bacteria in the

stomach, particularly gram-negative bacilli that originate in the duodenum.

The extent to which reflux of gastric contents and secretions occurs even in healthy individuals suggests that these critically ill patients are susceptible to aspiration events. Critically ill intubated patients lack the ability to defend their airway. Esophageal reflux and aspiration of gastric contents along the endotracheal tube may lead to endobronchial colonization and pneumonia or may precipitate pneumonia due to the decreased bacterial killing in the low-acid environment. Nevertheless, a meta-analysis of studies published prior to 1990 did not find an increased incidence of hospital-acquired pneumonia with elevation of gastric pH, although there was a trend towards a reduced rate of pneumonia with the prophylactic use of sucralfate as compared with pH-altering drugs.

The Surviving Sepsis Campaign Guidelines were produced after a thorough review of the literature including peptic ulcer disease prophylaxis. They conclude, “H2 receptor inhibitors are more efficacious than sucralfate and are the preferred agents. Proton pump inhibitors have not been assessed in a direct comparison with H2 receptor antagonists and, therefore, their relative efficacy is unknown. They do demonstrate equivalency in ability to increase gastric pH.” [1]

While it is unclear if there is any association with decreasing rates of ventilator acquired pneumonia, our experience is that when applied as a package of interventions for ventilator care, the rate of pneumonia decreases precipitously. The intervention remains excellent practice in the general care of ventilated patients.

References:

1. Dellinger RP, Carlet JM, Masur H, et al. Surviving Sepsis Campaign guidelines for management of severe sepsis and septic shock. *Crit Care Med.* Mar 2004;32(3):858-873.
2. Cook DJ, Laine LA, Guyatt GH, Raffin TA. Nosocomial pneumonia and the role of gastric pH: A meta-analysis. *Chest.* 1991;100:7.
3. Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. *Am J Respir Crit Care Med.* 2005;171:388.

Tips

- Include peptic ulcer disease prophylaxis as part of your ICU order admission set and ventilator order set. Make application of prophylaxis the default value on the form.
- Include peptic ulcer disease prophylaxis as an item for discussion on daily multidisciplinary rounds.
- Empower pharmacy to review orders for patients in the ICU to ensure that some form of peptic ulcer disease prophylaxis is in place at all times on ICU patients.
- Post compliance with the intervention in a prominent place in your ICU to encourage change and motivate staff

Ventilator Bundle: Deep Venous Thrombosis Prophylaxis

Deep venous thrombosis prophylaxis is an integral part of the [IHI Ventilator Bundle](#) and has been correlated with reduction in the rate of ventilator-acquired pneumonia. Applying deep venous thrombosis prophylaxis is an appropriate intervention in all patients who are sedentary, however the higher incidence of deep venous thrombosis in critical illness justifies greater vigilance.

The risk of venous thromboembolism is reduced if prophylaxis is consistently applied. A clinical practice guideline issued as part of the Seventh American College of Chest Physicians Conference on Antithrombotic and Thrombolytic Therapy recommends prophylaxis for patients undergoing surgery, trauma patients, acutely ill medical patients, and patients admitted to the intensive care unit. The level of cited evidence was that of several randomized control trials.[1]

While it is unclear if there is any association with decreasing rates of ventilator acquired pneumonia, our experience is that when applied as a package of interventions for ventilator care, the rate of pneumonia decreases precipitously. The intervention remains excellent practice in the general care of ventilated patients.

Important considerations include that the risk of bleeding may increase if anticoagulants are used to accomplish prophylaxis. Often times, sequential compression devices (a.k.a. "venodynes" or "pneumoboots") are not applied to patients when they go to or return from procedures.

References:

1. Geerts WH, Pineo GF, Heit JA, et al. Prevention of venous thromboembolism: the Seventh ACCP Conference on Antithrombotic and Thrombolytic Therapy. *Chest*. Sep 2004;126(3 Suppl):338S-400S.

Tips

- Include deep venous prophylaxis as part of your ICU order admission set and ventilator order set. Make application of prophylaxis the default value on the form.
- Include deep venous prophylaxis as an item for discussion on daily multidisciplinary rounds.
- Empower pharmacy to review orders for patients in the ICU to ensure that some form of deep venous prophylaxis is in place at all times on ICU patients.
- Post compliance with the intervention in a prominent place in your ICU to encourage change and motivate staff.

IHI Ventilator Bundle: Daily Oral Care with Chlorhexidine

IHI added this element to the [Ventilator Bundle](#) in May 2010 following continued review of the literature and use of the element in the IHI Ventilator Bundle in Scotland for over a year. The recommended chlorhexidine solution strength is 0.12%.

Dental plaque biofilms are colonized by respiratory pathogens in mechanically ventilated patients. Dental plaque develops in patients that are mechanically ventilated because of the lack of mechanical chewing and the absence of saliva, which minimizes the development of biofilm on the teeth. Dental plaque can be a significant reservoir for potential respiratory pathogens that cause ventilator-associated pneumonia (VAP). Chlorhexidine antiseptic has long been approved as an inhibitor of dental plaque formation and gingivitis. As early as 1996, DeRiso and colleagues published a study that provided evidence to support the use of 0.12% chlorhexidine oral rinse as a prophylactic measure to reduce nosocomial respiratory tract infections in cardiac surgery patients.[1]

Since that time there has been much discussion about the utilization of chlorhexidine as an important adjunct to oral hygiene, but there have been few studies published that provide firm evidence that the use of chlorhexidine as a decontamination antiseptic reduces the incidence of ventilator-associated pneumonia. Chlorhexidine has been studied in two strengths: 0.12% and 0.2%. The US Food and Drug Administration recommends 0.12% oral chlorhexidine for use as mouth rinse. In a meta-analysis published in 2007 by Chan and colleagues in the *British Medical Journal*, eleven studies were evaluated for effect of oral decontamination on the incidence of ventilator-associated pneumonia and mortality in mechanically ventilated adults. Results of that analysis concluded that oral decontamination of mechanically ventilated adults using chlorhexidine is associated with a lower risk of ventilator-associated pneumonia.[2]

There is little if any evidence of other oral care processes having an effect on the development of VAP, but it makes sense that good oral hygiene and the use of antiseptic oral decontamination reduces the bacteria on the oral mucosa and the potential for bacterial colonization in the upper respiratory tract. This reduction in bacteria has been shown to reduce the potential for the development in ventilator-associated pneumonia for patients on mechanical ventilation.

Zero VAP Rate in the ICU by Reducing Time on Sedation

Mercy Hospital

Buffalo, New York, USA

The Mercy Hospital team is a charter member of IHI's [Passport](#) program.

Mercy Hospital's strategy to eliminate ventilator-associated pneumonia (VAP) for patients in the intensive care unit (ICU) includes reliable implementation of the [IHI Ventilator Bundle](#), with a special focus on reducing the amount and duration of sedation for patients on ventilators in the ICU. One of the key elements of the IHI Ventilator Bundle is daily "sedation vacations" and assessment of readiness to extubate the patient.

Linda Horton, Vice President of Clinical Innovations and Outcomes, credits her organization's participation in the [IHI Expedition on Preventing Complications in the ICU](#) for the increase in the reliability of their care for ICU patients. After their Expedition participation, their VAP rate has stayed at zero for almost a year and a half.

Aim

To reduce the risk of developing hospital acquired ventilator pneumonia for patients in ICU, with 50 percent reduction in the amount and duration of sedation and 30 percent reduction in ventilator days by September 2011.

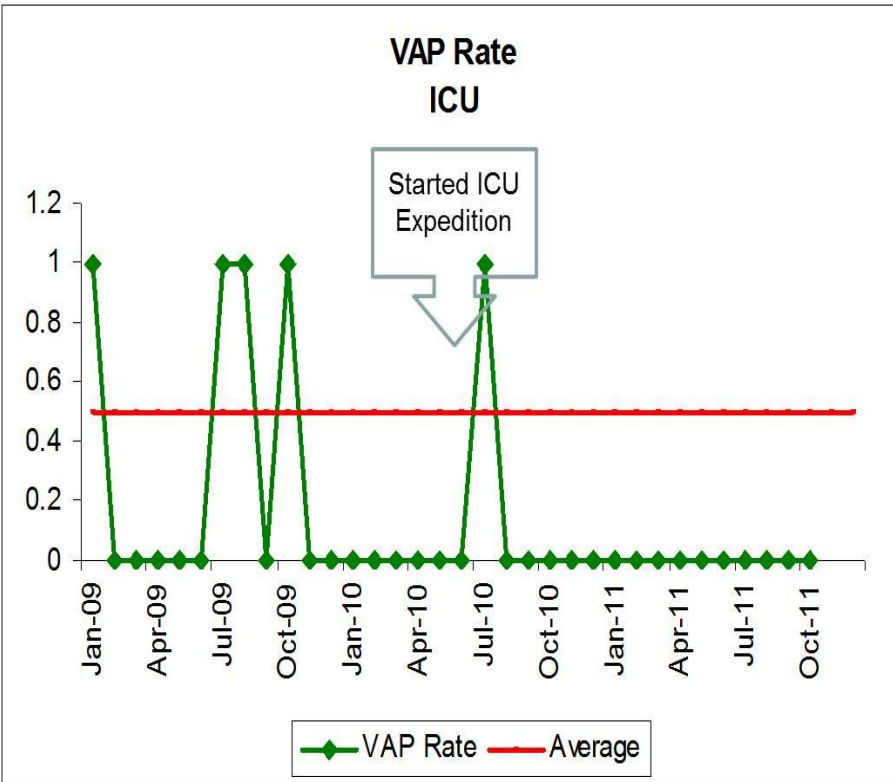
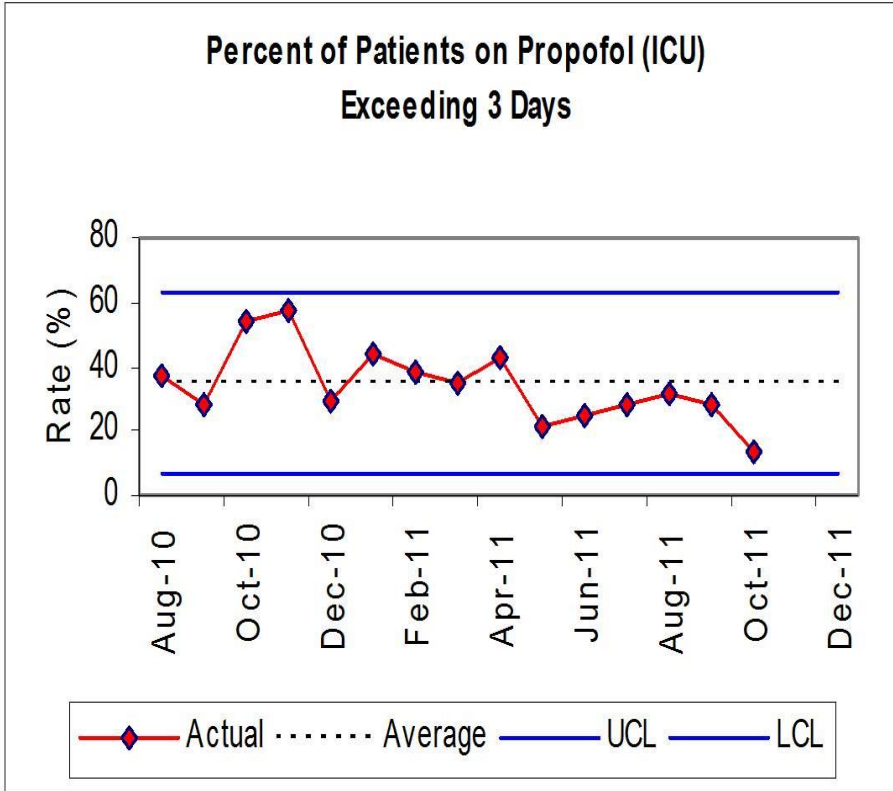
Actions Taken

- Physician leader rounding daily
- Use of ventilator order sheet
- Protocol-driven sedation tools for propofol use

- Support from interdisciplinary team: pharmacy, respiratory therapy, nurses, physicians
- Education to associates on MAAS scores
- Daily sedation vacations scheduled
- Communication
- Streamline documentation
- Ventilator Bundle education
- Implementation of oral care policy and oral care kits every 4 hours
- Head of bed elevation: 30 degrees

Results

The Mercy team tracked data on the percent of their patients on propofol exceeding three days. They report a 77.2 percent reduction in days on propofol and an 82.2 percent reduction in doses dispensed. They also report that the VAP rate for ICU patients has been at zero for almost a year and a half.



ICU Daily Goals Worksheet

Johns Hopkins University, Submitted by Peter Pronovost, MD, PhD
Baltimore, Maryland, USA

Background

The tool was developed as part of a prospective cohort study in collaboration with the Volunteer Hospital Association (VHA), the Institute for Healthcare Improvement (IHI), and Johns Hopkins Hospital's (JHH) 16-bed surgical oncology ICU. All patients admitted to the ICU were eligible.

The main outcome variables were ICU length of stay (LOS) and percent of ICU residents and nurses who understood the goals of care for patients in the ICU. Baseline measurements were compared with measurements of understanding after implementation of a daily goals form.

At baseline, less than 10 percent of residents and nurses understood the goals of care for the day. After implementing the daily goals form, greater than 95 percent of nurses and residents understood the goals of care for the day. After implementation of the ICU Daily Goals Worksheet, ICU LOS decreased from a mean of 2.2 days to 1.1 days.

Directions

During daily rounds in the ICU, have the ICU team visit each patient and develop a plan of care for the day and complete the ICU Daily Goals Worksheet. The fellow or attending physician should sign the worksheet and hand it to the patient's nurse before moving on to the next patient.

All providers, physicians, nurses, respiratory therapists, and pharmacists should review the goals for the day and initial the worksheet three times a day. The team should update the worksheet if the goals of care change.

See [“Improving Communication in the ICU Using Daily Goals”](#) for a complete discussion of the development and use of the ICU Daily Goals Worksheet.

Daily Goals Worksheet

Patient Name _____
Date ____/____/____

Room Number _____

---Initial as goals are reviewed ----

GOAL	NOTES	---Initial as goals are reviewed ----		
		0700-1500	1500-2300	2300-0700
What needs to be done for the patient to be discharged from the ICU?				
What is this patient's greatest safety risk?				
Pulmonary/Ventilator: HOB 30 degrees or greater				
Sedation Vacation and Assessment of Readiness to Extubate				
PUD Prophylaxis				
DVT Prophylaxis				
Oral care with chlorhexidine				
Cardiac Rhythm, Hemodynamics				
Volume Status, net goal for 12 MN				
Neuro/Pain Mgt/Sedation				

GI/ Nutrition/Bowel Regimen				
Mobilization/OOB				
ID, Cultures, Drug levels				
Medication changes (Can any be discontinued?)				
Tests/Procedures Today				
Review scheduled labs. Can any be discontinued?				
Morning labs and PCXR				
Consultations				
Can central lines or other catheters/tubes be DC'd?				
Attending up to date?				
Family Updated?				
Any social issues to address?				
Emotional/spiritual issues addressed?				
Skin Care Addressed?				
Code Status Addressed?				
Advanced Directive in place?				
Parameters for calling MD				

Ventilator Bundle Checklist

Dominican Hospital. Santa Cruz, California, USA

Use the Ventilator Bundle Checklist to help track your organization's compliance with implementing *each* element of the [IHI Ventilator Bundle](#). The greater the level of compliance with *all* of the items in the bundle, the better the reduction in the ventilator-associated pneumonia rate.

*NOTE: The checklist is particularly effective if used in conjunction with the [Daily Goals Worksheet](#) that can be completed during daily rounds on the patient.

VENTILATOR BUNDLE CHECKLIST (Individual Patient)										
Patient: _____										
Admit Date: _____										
<u>ICU Day</u>	1	2	3	4	5	6	7	8	9	10
1. Head of the Bed 30°	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. Daily sedative interruption and daily assessment of readiness to extubate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. PUD Prophylaxis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. DVT Prophylaxis	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. Daily Oral Care with Chlorhexidine	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Adapted from: Dominican Hospital Santa Cruz, California, USA										

Implement an Intensivist Model in the Intensive Care Unit (ICU)

Establishing an organized system of ICU care has improved ICU mortality and length of stay. The ICU care team and executive leadership should work towards developing systems that assure continuous improvement. In this regard, the type of physician caring for critically ill patients matters.

ICUs are traditionally described as “open” or “closed” units. Open units are those ICUs where any physician in virtually any field may see a patient and write orders on that patient. Doctors of any stripe may admit patients to these ICUs with few limitations. Doctors are not required to obtain critical care consultations.

Closed ICUs are those where physicians are required to admit patients to an intensive care service. Physicians must allow the ICU staff physicians to be the primary care agents for the patient ultimately responsible for all medical decision making. Other disciplines, including the general medicine or family practice service, may consult on the patient during the ICU stay.

Reorganizing ICU physician services in one organization by implementing an intensivist infrastructure has resulted in a 14 percent absolute risk reduction in mortality [Pronovost P, Berenholtz S. A Practical Guide to Measuring Performance in the Intensive Care Unit. VHA Research Series. 2002;(2):29.].

Changes for Improvement Require Critical Care Consultations

Improving care to critically ill patients may require a stepwise process. The overall goal is to implement an organized system of ICU care. The first step in this process should include directly impacting the care of ICU patients by involving those practitioners who are best trained in their care.

Perhaps the easiest solution in this regard is to require that all patients admitted to the ICU receive consultation from a critical care physician with ongoing daily involvement. Until an intensivist-led service can be developed, which should be the goal, consultative medicine stands to improve the chances that patients admitted by a generalist or physician from another specialty receive specific interventions related to their critical illness.

In order to achieve maximum effectiveness, the consultation should continue daily until the patient is discharged from the ICU. While the admitting physician retains ultimate responsibility for the care of the patient in this system, his or her admitting physician can benefit from the assistance of the intensivist.

Tips:

- Work with the chiefs of the Departments of Medicine and Surgery to require critical care consultations on all patients admitted to the ICU.
- Use initiatives endorsed by insurers and private organizations such as the [Leapfrog Group](#) to justify your approach to administrators.
- Require that critical care consultations continue daily until patient discharge from the ICU.
- Don't stop with consultations: make consultation a bridge to development of an intensivist-led service.

Develop an Intensivist-Led Service

Improving care to critically ill patients may require a stepwise process. The overall goal is to implement an organized system of ICU care. A temporary step in the process of ICU care improvement may involve mandatory critical care consultation. The next step involves working to establish an intensivist-led model to eliminate variability in the provision of ICU care to critically ill patients.

Critically ill patients who are admitted to intensivists fair better than those who are primarily cared for by other doctors [Pronovost P, Berenholtz S. A Practical Guide to Measuring Performance in the Intensive Care Unit. VHA Research Series. 2002;(2):29]. The reasons for this may be varied, however this concept only stands to reason. Critically ill patients are characterized by complex physiologic and hemodynamic perturbations. Critical care physicians are best trained to handle these matters routinely.

Other physicians' opinions and voices should remain active in their patients' care during the ICU stay. The critical care physician should seek consultation from generalists and specialty services as needed.

Tips:

- Use initiatives endorsed by insurers and private organizations such as the Leapfrog Group to justify your approach to administrators.
- Open discussions regarding transforming care with key players in the Departments of Medicine and Surgery.
- If your hospital has a successful hospitalist service for general medical patients, use the success of this model as leverage for establishment of dedicated intensivist care.
- Cite cost savings as a potential advantage in this model as inappropriate, lengthy, and costly care is reduced by improved decision making.
- Track inconsistencies in care plans that can cause confusion among staff and can fragment the team approach. Work towards an inclusionary environment where established relationships and team work reduces errors and proactive care becomes the norm.

Implement Multidisciplinary Rounds

Multidisciplinary rounds (MDR) enable several key members of the team caring for patients to come together and offer expertise in patient care. Too frequently physicians alone prescribe care for patients without the input of other providers such as nursing, pharmacy, respiratory therapy, nutrition, physical therapy, occupational therapy, and social work. Even the most efficient physicians stand to benefit from the counsel of these providers to provide the best care for patients.

This intervention has proven successful in medical and surgical settings. Efficient patient care depends on close communication between the physicians, nursing, physical therapy, and discharge planners. Many times, the number of services involved and the workload of each service slows down communication in patient care. In trauma care, multidisciplinary rounds have been demonstrated to have a dramatic effect on patient flow. While maintaining their daily census, one team reported a 36 percent increase in patient volume and a 15 percent decrease in length of stay. "Bypass" status-inability to accept admissions was virtually eliminated. What is more, this effect has been sustained over time.[1]

Vazirani et al. demonstrated that using multidisciplinary rounds in an acute care medical unit improved satisfaction with care for physicians, nurses, and patients. In addition, overall quality of care is improved with the addition of a nurse practitioner to each inpatient medical team, the appointment of a hospitalist medical director, and the institution of daily multidisciplinary rounds. The multidisciplinary intervention resulted in better communication and collaboration among the participants.[2]

References:

1. Dutton RP, Cooper C, Jones A, et al. Daily multidisciplinary rounds shorten length of stay for trauma patients. *J Trauma*. 2003 Nov;55(5):913-919.

2. Vazirani S, Hays RD, Shapiro MF, et al. Effect of a multidisciplinary intervention on communication and collaboration among physicians and nurses. *Am J Crit Care*. 2005 Jan;14(1):71-77.

Convene A Multidisciplinary Rounds Conference

Convening a conference of involved parties may assist in the establishment of multidisciplinary rounds (MDR). There are some barriers to overcome depending on the type of unit.

Open units (non-intensivist-led units in which any physician may admit and write orders) generally will have more challenges to overcome in establishing multidisciplinary rounds. However our experience is that persistence will generate physician buy-in and encourage their respect for the rounding process. Rounds may have to begin without physician input and a summary of recommendations brought to their attention. Over time, many physicians begin to attend the rounds more regularly to learn about best treatment options.

Closed units (intensivist-led units, or units requiring critical care consultation, in which a “team” writes orders only) generally have greater ability to begin multidisciplinary rounds without resistance.

Both types of units will benefit from the changes however. Issues regarding multidisciplinary rounds that need to be resolved before the first meeting include who will participate in rounds, what is the focus, where rounds will occur, when (how often) they will take place, and how MDR will be conducted.

Who:

- Intensivists, generalists, ICU nurses, pharmacists, respiratory therapists
- Nutritionists, social workers, case managers
- Family members

What:

- **Patient's Preferences and Goals:** These are essential to identify appropriate care that the patient would choose rather than the providers' preferences. In ICU care this will often involve meeting with family members who should be invited to attend certain MDR sessions.
- **Patient's Care Needs:** Once a patient's preferences and goals are understood plans can be made to medically meet those needs.
- **Acuity Assessment and Discharge Planning:** Ongoing planning for discharge is critical to ensure the care plan follows through to the wards and then to rehabilitation and home.

Where:

- Rounds are best held at the patient bedside.
- Large teams may need to meet in a separate conference area.

When:

- A daily MDR conference is optimal.
- Two to three times weekly may be an acceptable alternative.

How:

- MDR may be integrated into physicians' daily patient care rounds.
- If your ICU lacks a daily rounding structure, these rounds can occur independently from such a structure at a designated time.

Tips:

- Agree to name a "captain of the ship" in the event multiple consultants are involved so that a coordinated and cohesive treatment plan is implemented. This is usually one physician — the physician of record. This individual

writes orders on the patient based upon the recommendations elucidated during multidisciplinary rounds.

- Identify and present issues to the physician at multidisciplinary rounds.
- Expect the “captain of the ship” to rely upon MDR team members: a professional crew of many consultants (“shipmates and deck hands”) who make certain that things work properly and assure “smooth sailing.”
- Monitor the progress of each patient closely by maintaining detailed progress notes. Check for concurrence with daily goals identified during multidisciplinary rounds.
- Approach and redirect providers when protocols are not followed. Have the ICU nurse manager or charge nurse consult with physicians and thereby improve compliance with quality of care goals.
- Focus on discharge planning to assure safe, adequate follow-up care and the continuation of services into the outpatient setting

Implement Daily Goals Assessment

Daily goals assessment allows teams to keep track of plans established either on patient care rounds and/or multidisciplinary rounds and to verify their completion. The intent is to establish 1 or 2 appropriate, explicit daily goals for patients and improve their overall care. In addition, involving the family in establishing daily goals and informing the family of care plans can enhance satisfaction for everyone.

Daily goal setting is usually done by working from a daily goals worksheet. Keeping the patients' daily goal worksheets up-to-date enhances several processes:

- Allows better documentation and communication
- Permits evaluation of patient safety risks
- Sharpens staff attention to early changes in patients that may be worrisome
- Enhances communication among team members and patient/family

Create a Daily Goals Worksheet

Creating a daily goals worksheet assists care teams to keep track of plans established either on patient care rounds and/or multidisciplinary rounds and to verify their completion. In addition, patient safety is enhanced identifying potential safety risks. Duplicate efforts are diminished and length of stay is decreased.

A daily goals worksheet may be individualized to your particular unit and the specific needs and traditions of your hospital. Below are some considerations for daily goals worksheets:

- What work needs to happen for the patient today?

- What is the patient's greatest safety risk?
- If applicable, are all elements of the appropriate bundle completed?
- What are the discharge plans for the patient (either from the critical care unit or the discharged home)?
- Catheter — site care, inspection, consideration for removal?
- Communication/family issues — have we talked to the family today?

Implement Effective Glucose Control

Latest Evidence

Due to IHI's commitment to adjust recommendations based on emerging evidence-based medicine, we are updating our glucose control recommendations following the publication of the NICE-SUGAR study in the *New England Journal of Medicine* in March 2009.[1] We will continue to adjust recommendations as new evidence emerges. The updated recommendation follows.

Introduction

Effective glucose control in the intensive care unit (ICU) has been shown to decrease morbidity across a large range of conditions and also to decrease mortality.

Hyperglycemia, caused by insulin resistance in the liver and muscle, is a common finding in ICU patients. Some have considered it to be an adaptive response, providing glucose for the brain, red blood cells, and wound healing. Traditionally, hyperglycemia has only been treated when blood glucose increases to >215 mg/dL (>12 mmol/L). Conventional wisdom in the ICU has been that some degree of hyperglycemia is beneficial and that hypoglycemia is dangerous and should be avoided. The extent of appropriate glucose control has been evaluated in recent years.

Initial Investigations – Intensive Insulin Therapy

An initial investigation by Van den Berghe and colleagues [2] suggested that controlling blood glucose levels by intensive insulin therapy decreased mortality and morbidity in surgical critically ill patients. The trial was a large single-center study of postoperative surgical patients. The design employed a continuous infusion of insulin to maintain glucose between 80 and 110 mg/dL (4.4–6.1 mmol/L). Exogenous glucose was begun simultaneously with insulin, with

frequent monitoring of glucose (every 1 hour) and intensity of monitoring was greatest at the time of initiation of insulin. This protocol called for implementing a strategy to maintain normoglycemia with an insulin infusion while providing for normal intake of glucose (9 g/hr) and calories (19 kcal·kg⁻¹·day⁻¹).

A total of 35 of 765 patients (4.6 percent) in the intensive insulin group died in the ICU in Van den Berghe et al., compared with 63 patients (8.0 percent) in the conventional therapy group.

Intensive insulin therapy halved the prevalence of:

- Bloodstream infections
- Prolonged inflammation
- ARF requiring dialysis or hemofiltration
- Critical illness polyneuropathy
- Transfusion requirements

Patients receiving intensive insulin therapy were also less likely to require prolonged mechanical ventilation and intensive care. Rigorous insulin treatment reduced the number of deaths from multiple-organ failure with sepsis, regardless of whether there was a history of diabetes or hyperglycemia.

Surgical vs. Medical Patients

The same protocol used in the first Van den Berghe trial for surgical patients was subsequently tested in medical patients.[3]

Patients who were considered to need intensive care for at least three days were enrolled in a prospective, randomized, single-center, controlled study. On admission, patients were randomly assigned to strict normalization of blood glucose levels (80 to 110 mg per deciliter [4.4 to 6.1 mmol per liter]) with the use of insulin infusion or conventional therapy (i.e., insulin administered when the blood

glucose level exceeded 215 mg per deciliter [12 mmol per liter], with the infusion tapered when the level fell below 180 mg per deciliter [10 mmol per liter]).

Intensive insulin therapy reduced blood glucose levels but did not significantly reduce in-hospital mortality (40.0 percent in the conventional-treatment group vs. 37.3 percent in the intensive-treatment group, $P=0.33$). However, morbidity was significantly reduced by the prevention of newly acquired kidney injury, accelerated weaning from mechanical ventilation, and accelerated discharge from the ICU and the hospital.

Although length of stay in the ICU could not be predicted on admission, among 433 patients who stayed in the ICU for less than three days, mortality was greater among those receiving intensive insulin therapy. In contrast, among 767 patients who stayed in the ICU for three or more days, in-hospital mortality in the 386 who received intensive insulin therapy was reduced from 52.5 to 43.0 percent ($P=0.009$) and morbidity was also reduced.

The authors concluded that intensive insulin therapy significantly reduced morbidity but not mortality among all patients in the medical ICU. Although the risk of subsequent death and disease was reduced in patients treated for three or more days, these patients could not be identified before therapy.

NICE-SUGAR Study

Based on the foregoing studies, most clinicians believed that there was a benefit to glucose control in terms of mortality and morbidity. However, the optimal target range for blood glucose in critically ill patients remained unclear.

The NICE-SUGAR study investigators [1] chose to evaluate whether there was a difference in mortality between subjects randomly assigned to either intensive glucose control, with a target blood glucose range of 81 to 108 mg per deciliter (4.5 to 6.0 mmol per liter), or conventional glucose control, with a target of 180 mg or less per deciliter (10.0 mmol or less per liter). To be considered, patients were expected to require treatment in the ICU on 3 or more consecutive days.

Of the 6,104 patients who underwent randomization, 3,054 were assigned to undergo intensive control and 3,050 to undergo conventional control. A total of 829 patients (27.5 percent) in the intensive-control group and 751 (24.9 percent) in the conventional-control group died. Thus, the odds of dying with intensive control were 1.14 times greater than with conventional control ($P=0.02$). In addition, severe hypoglycemia (blood glucose level of 40 mg per deciliter [2.2 mmol per liter]) was reported in 206 of 3,016 patients (6.8 percent) in the intensive-control group and in 15 of 3,014 patients (0.5 percent) in the conventional-control group ($P<0.001$). Thus, the incidence of hypoglycemia was lower in the conventional group.

With regard to morbidity and length of stay, NICE-SUGAR demonstrated that there was no significant difference between the two treatment groups in the median number of days in the ICU or hospital, or the median number of days of mechanical ventilation or renal-replacement therapy.

The NICE-SUGAR investigators concluded that that intensive glucose control increased mortality among adults in the ICU and that a blood glucose target of 180 mg or less per deciliter resulted in lower mortality than did a target of 81 to 108 mg per deciliter.

More details about the study can be found on the [NICE-SUGAR Study website](#).

Overall Recommendation

Evaluating the evidence, it is clear that the NICE-SUGAR trial is the most complete study on glucose control in ICU patients given its inclusion of multiple sites, a more general patient population, a much larger number of patients, etc., compared to other trials. As such, we recommend teams seeking to implement glucose control set a goal of less than 180 mg/dL for critically ill patients.

Nevertheless, there is not great clarity about lower guidelines following the NICE-SUGAR study, given that ranges such as 100 to 140 mg/dL were not studied. Hospitals can review and adapt existing protocols (including the protocol in the NICE-SUGAR study) and take into account their own feeding regimens and local

expertise and experience with glucose control and avoidance of hypoglycemia. Hospitals can consider settings goal ranges such as 60 to 180, 100 to 140, 100 to 180, or 140 to 180 as needed to avoid severe (less than 40 mg/dl) hypoglycemia. The effort should be to avoid hypoglycemia in at least 99 percent of patients.

Clinical Evidence

1. NICE-SUGAR Study Investigators, Finfer S, Chittock DR, Su SY, et al. [Intensive versus conventional glucose control in critically ill patients](#). New England Journal Medicine. 2009 Mar 26;360(13):1283-1297.
2. Van den Berghe G, Wouters P, Weekers F, et al. [Intensive insulin therapy in critically ill patients](#). New England Journal of Medicine. 2001 Nov 8;345(19):1359-1367.
3. Van den Berghe G, Wilmer A, Hermans G, et al. [Intensive insulin therapy in the medical ICU](#). New England Journal of Medicine. 2006 Feb 2;354(5):449-461.

Establish a Glycemic Control Policy in Your ICU

The literature suggests that appropriate glycemic control in the ICU reduces morbidity and overall mortality in the critically ill. [1,2,3] Nonetheless, the difficulties in establishing a working glycemic control policy in the ICU are challenging. Typically, clinicians' fear of inducing hypoglycemia is the first obstacle to overcome in launching an improvement effort. Doctors remain wary of inducing hypoglycemia and may not have confidence in selecting appropriate doses. Nurses fear hypoglycemia and remain concerned about protocolized adjustments to intravenous insulin rates of administration. The balance of evidence suggests, however, that once these barriers are addressed, ICU patients receive better care with appropriate glycemic control.

Insulin, Glucose Co-Administration

Studies supporting the role of glycemic control have variably used continuous infusion of insulin along with glucose or enteral nutrition as a feeding source. The methods used in the foundational study by Van den Berghe and colleagues employed a continuous infusion of glucose or enteral nutrition in all subjects. Insulin was infused concomitantly to maintain glucose between 80 and 110 mg/dL (4.4–6.1 mmol/L). [1] However, the NICE-SUGAR study left nutritional management to the discretion of treating clinicians in the individual ICUs of the 42 hospitals participating in the trial. These investigators reported that during the first 14 days after randomization, the mean daily amount of nonprotein calories administered was 891±490 kcal in the intensive-control group and 872±500 kcal in the conventional-control group (P = 0.14). [3] In the Van den Berghe trials, exogenous glucose was begun simultaneously with insulin, with frequent monitoring of glucose (every 1 hour) and intensity of monitoring was greatest at the time of initiation of insulin. [1,2]

Given the variation in feeding protocols, it is unclear what the optimal feeding recommendation is during administration of intravenous insulin to maintain glucose control. However, the NICE-SUGAR study again allowed for the type of variation that might typically be seen in everyday use across hospitals.

Protocols and Frequency of Monitoring Serum Glucose

More details about the NICE-SUGAR protocols are available on the [NICE-SUGAR Study website](#). Control of blood glucose was achieved with the use of an intravenous infusion of insulin in saline. In the group of patients assigned to undergo conventional glucose control, insulin was administered if the blood glucose level exceeded 180 mg per deciliter; insulin administration was reduced and then discontinued if the blood glucose level dropped below 144 mg per deciliter (8.0 mmol per liter). Blood glucose levels in each patient were managed as part of the normal duties of the clinical staff at the participating center. In the Van den Berghe protocol, glucose levels were monitored frequently after initiation of the protocol (every 30 to 60 minutes) and on a regular basis (every 4 hours) once the blood glucose concentration had stabilized. This protocol was provided by the investigators as an appendix to their study and can be found on the website of the [New England Journal of Medicine](#).

Watch for Hypoglycemia

We recommend clinicians pay particular attention to glycemic control to prevent metabolic complications and to ensure adequate nutritional support. Hypoglycemia may occur when controlling glucose values in critically ill patients. In the NICE-SUGAR study, severe hypoglycemia (defined as a blood glucose level ≤ 40 mg per deciliter [2.2 mmol per liter]) was recorded in 206 of 3,016 patients (6.8 percent) undergoing intensive glucose control, as compared with 15 of 3,014 patients (0.5 percent) undergoing conventional control (odds ratio, 14.7; 95 percent CI, 9.0 to 25.9; $P < 0.001$). The recorded number of episodes of severe hypoglycemia was 272 in the intensive-control group, as compared with 16 in the conventional-control group. [3]

Compliance with your organization's protocol may be better if appropriate safety controls are built into your management strategy. Adequate staff education and a written, explicit protocol are prerequisites to beginning your work on glucose control and may help to prevent episodes of hypoglycemia.

Nutritional Support

A strategy of glycemic control should include efforts to provide adequate nutrition with the preferential use of the enteral route. A strategy of appropriate glycemic control should be carefully coordinated with particular patients' level of nutritional support and metabolic status, which changes frequently in critically ill patients.

Clinical Evidence

1. Van den Berghe G, Wouters P, Weekers F, et al. [Intensive insulin therapy in critically ill patients](#). New England Journal of Medicine. 2001 Nov 8;345(19):1359-1367.
2. Van den Berghe G, Wilmer A, Hermans G, et al. [Intensive insulin therapy in the medical ICU](#). New England Journal of Medicine. 2006 Feb 2;354(5):449-461.
3. NICE-SUGAR Study Investigators, Finfer S, Chittock DR, Su SY, et al. [Intensive versus conventional glucose control in critically ill patients](#). New England Journal Medicine. 2009 Mar 26;360(13):1283-1297.

Tips

- Create a standardized protocol that prompts users to initiate an insulin drip for critically ill patients in order to target serum glucose consistently less than 180 mg/dl.

- Design and implement a glucose control protocol using an insulin drip and permitting titration and adjustment by ICU nurses to safely accomplish tight glucose control.
- Make use of continuous administration of glucose or enteral feeding while the insulin drip is active, with frequent glucose monitoring by finger stick and a specific treatment plan for hypoglycemia.
- Educate the nursing staff about the benefits of tight glucose control and relieve the fear of increasing the incidence of hypoglycemia. Maintaining proper glycemic control in patients can intimidate staff with requirements to titrate a potentially lethal medicine without moment-to-moment physician management. That fear can defeat the success of the project.
- Work closely with nursing to create the protocols to make sure the increased burden of frequent glucose checks can be handled in their workflow.

Examples of Tests of This Change

Example: Implement a process to manage blood glucose less than 180 mg/dl consistently in critically ill patients.

Method: Use [Plan-Do-Study-Act cycles](#) to implement change progressively to alleviate physician and nursing concerns about hypoglycemia and insulin drip rate adjustments.

- Cycle 1: Establish a system to monitor and document blood glucose measurements in critically ill patients.
- Cycle 2: Modify an adopted insulin drip protocol to control the glucose in a hyperglycemic patient less than 180 mg/dL and send it out for comment and buy-in to practitioners who will use the protocol.
- Cycle 3: Test the protocol on one or two patients and modify as needed to improve safety and objections to work flow problems.

- Cycle 4: Because of problems with frequent glucometer checks and difficulties in access to the instruments purchase more for the unit.
- Cycle 5: Because there is overshoot of the serum glucose level target when 50 percent dextrose is used for hypoglycemia in the test patients, modify the dose in the protocol to reduce this problem and measure the results.
- Cycle 6: Continue small tests and modifications until safety and consistency is established then release for general use.

Create a Reporting System

<http://www.ihl.org/knowledge/Pages/Changes/CreateaReportingSystem.aspx>

In a culture of safety, staff members are aware of safety issues and are free to report conditions that could lead to near misses or actual adverse events. This open exchange of information requires the management to have a non-punitive response philosophy that rewards reporting of safety issues and events and does not punish staff members involved in errors or adverse events related to system failures.

Tips

- Communicate the reporting policy to the staff during [Patient Safety Leadership WalkRounds™](#).
- Adopt a non-punitive reporting policy.
- Reinforce the non-punitive management philosophy by asking staff members who have reported safety issues, near misses, or adverse events to share their story with others, including how the management supported them.
- Consider staff members' safety reports — and their involvement in other safety initiatives — favorably in their annual performance reviews.
- Train managers to identify human factors and system failures in errors and adverse events.
- Let reporters know something will be done with their report that the system works. That way they feel that their report will be useful.

Conduct Patient Safety Leadership WalkRounds™

Senior leaders wishing to demonstrate their commitment to safety and learn about the safety issues in their own organization can do so by making regular rounds for the sole purpose of discussing safety with the staff. During the WalkRounds™, the communication should go two ways, with both the executives and the staff talking honestly and listening carefully. Many organizations have found Patient Safety Leadership WalkRounds™ especially effective in conjunction with [Safety Briefings](#) which often provide material for executives to start discussions.

Tips

- Get a commitment from senior executives for an hour every week. The WalkRounds™ may be rescheduled but never canceled.
- Keep discussions focused on safety; don't dilute the safety message by trying to cover other topics.
- Involve all the senior executives in the organization, not just the chief executive officer.
- Communicate with managers so they understand why senior executives are visiting their departments.
- Make sure that senior executives follow up and [provide feedback to staff](#) about issues raised during the WalkRounds™.
- Institute regular [safety briefings](#). Pass along issues raised in the briefings (with names of the contributing staff members withheld) to the executives to talk about on their WalkRounds™.
- Take a digital camera. It has been wonderful for PowerPoint presentations to

staff and quality council meetings. Pictures are worth a thousand words.

[Submitted by Marie Zappia Kuzmack, San Clemente Hospital]

- Prior to leaving the unit, have executive summarize the issues and ask staff to prioritize 2 to 3 items to be addressed. *[Submitted by: Eunice Jones, Catholic Healthcare Partners, Knoxville, TN]*

Changes to Prevent Surgical Site Infection

Effective surgical infection prevention requires redesigning systems to reduce risk factors and to optimize evidence-based processes of care. Essential process for prevention of surgical site infections are core measures in the [Surgical Care Improvement Project](#) and have been essential components in IHI surgical safety efforts: selection, timing, and duration of antimicrobial prophylaxis; glucose control in cardiac surgery; hair removal technique and other basic prevention strategies.

Changes for Improvement

Use Prophylactic Antibiotics Appropriately

An estimated 40–60 percent of Surgical Site Infections (SSIs) are preventable with appropriate use of prophylactic antibiotics. Overuse, under use, improper timing, and misuse of antibiotics occurs in 25–50 percent of operations. A large number of hospitalized patients develop infections caused by *Clostridium difficile*, and 16 percent of this type of infection in surgical patients can be attributed to inappropriate prophylaxis use alone. Inappropriate use of broad spectrum antibiotics or prolonged courses of prophylactic antibiotics puts all patients at even greater health risks due to the development of antibiotic-resistant pathogens.

- Designate responsibility and accountability for preoperative prophylactic antibiotic administration (e.g., preoperative nurse, circulating nurse, anesthesiologist) connected to key point in process
- Standardize administration process to occur with commonly performed activity within one hour prior to incision

- Through the use of antibiotic standing orders specific to surgical site, administer prophylactic antibiotics according to guidelines based on local consensus
- Make agreed upon antibiotics available in the operating room (OR)
- Standardize delivery process to ensure timely delivery of preoperative antibiotics to the holding area
- Provide visible reminder or checklist to give antibiotics on each case (e.g., brightly colored sticker)
- Ensure systematic documentation of antibiotic administration on every patient chart (paper or electronic)
- Develop system where antibiotic is hanging at head of patient's bed ready for administration
- Design protocols to deliver antibiotic to OR with patient
- Educate OR staff regarding the importance and reasoning of antibiotic timing, selection, and duration
- Provide feedback on prophylaxis compliance and infection data monthly
- Involve pharmacy staff to ensure timing, selection, and duration are maintained
- Institute a computerized physician order entry system with procedure-specific fields for antibiotic selection, timing, and duration
- Improve screening for allergies to beta lactam antibiotics to eliminate false positives
- Consider weight-based antibiotic dosing (higher dose for larger patients). As this may be cumbersome, may want to increase cephalosporins from 1 to 2 grams for all patients since minor issues around toxicity.

- Re-dose for longer surgeries (e.g., after 3 hours for short half-life cephalosporin)

Avoid Shaving Operative Site

In addition to the proper use of prophylactic antibiotics and good surgical technique, other factors under the control of the operative team have been demonstrated to affect significantly the risk of SSI. These other factors include avoiding hair removal at the operative site or when necessary, not using razors to remove hair. This preventive measure provides opportunities for improvement in most hospitals.

- Avoid hair removal unless necessary for the procedure.
- When necessary, remove hair with clippers right before surgery - but not in the operating room itself.
- Remove all razors from operating room and supply area.
- Establish protocol for when and how to remove hair in affected areas.
- Provide patient education and materials on appropriate hair removal techniques to prevent shaving at home.
- Avoid shaving heart surgery patients for EKG conducted shortly before surgery.

Maintain Postoperative Glucose Control for Major Cardiac Surgery Patients

Review of medical literature shows that the degree of hyperglycemia in the postoperative period was correlated with the rate of surgical site infection in patients undergoing major cardiac surgery (Lthan. Infection Control and Hospital Epidemiology. 2001;22:607; Dellinger. Infection Control and Hospital

Epidemiology. 2001;22:604). Other articles have demonstrated that stringent glucose control in surgical intensive care unit patients reduces mortality (Van den Berghe. New England Journal of Medicine. 2001;345:1359).

NOTE:

1. "Glucose control" is defined as serum glucose levels below 200 mg/dl, collected once on each of the first two postoperative days.
2. Tight glycemic control (e.g., using an insulin drip) is often performed in an intensive care setting or equivalent for safety.
 - Develop one protocol to be used for all surgical patients.
 - Regularly check preoperative blood glucose levels on all patients to identify hyperglycemia; this is best done early enough that the assessment of risk can be completed and treatment initiated if appropriate.
 - Assign responsibility and accountability for blood glucose monitoring and control

Use Basic Prevention Strategies from Category IA Center for Disease Control Recommendations

- Exclude patients with prior infections.
- Stop patient tobacco use prior to surgery.
- Apply sterile dressing for 24–48 hr.
- Shower with antiseptic soap.
- Provide positive pressure ventilation in OR with at least 15 air changes/hr.
- Keep OR doors closed.

- Use sterile instruments.
- Wear a mask.
- Cover hair.
- Prepare skin with appropriate agent.
- Wear sterile gloves; double-glove.
- Maintain short nails; remove artificial nails.
- Handle tissue gently.
- Ensure that surgeons/staff clean hands with appropriate agents and methods.
- Delay primary closure for heavily contaminated wounds.
- Exclude infected surgeons.
- Use closed suction drains (when used)

How-to Guide: Prevent Surgical Site Infections

Updated January 2012

Introduction

What is the Institute for Healthcare Improvement (IHI)?

The Institute for Healthcare Improvement (IHI) is a not-for-profit organization leading the improvement of health care throughout the world. IHI helps accelerate change by cultivating promising concepts for improving patient care and turning those ideas into action. Thousands of health care providers participate in IHI's groundbreaking work.

What is a How-to Guide?

IHI's How-to Guides address specific health care interventions that hospitals and/or entire health systems can pursue to improve the quality of health care while reducing unnecessary deaths, medical errors, and costs. These interventions align with several national initiatives of the Institute of Medicine (IOM), Agency for Healthcare Research and Quality (AHRQ), Centers for Medicare & Medicaid Services (CMS), the Joint Commission (JC), and the Centers for Disease Control (CDC), as well as the Department of Health and Human Services (HHS) "Partnership for Patients initiative"

This material was first developed for IHI's 5 Million Lives Campaign, a voluntary initiative to protect patients from five million incidents of medical harm from December 2006-December 2008. The 5 Million Lives Campaign was built on the 2004-2006 IHI 100,000 Lives Campaign. Both Campaigns involved thousands of hospitals and communities from around the United States in specific interventions. "Mentor Hospitals" showed marked improvement in one or more of the Campaign

interventions and volunteered to teach other hospitals. Many of their successful implementation stories and data have been included in this How-to Guide.

The Case for Preventing Surgical Site Infections

Surgical site infections are a frequent cause of morbidity following surgical procedures.¹ Surgical site infections have also been shown to increase mortality, readmission rates, length of stay, and costs for patients who incur them.² While nationally the rate of surgical site infection averages between two and three percent for clean cases (Class I/Clean as defined by CDC), an estimated 40 to 60 percent of these infections are preventable.

A review of the medical literature shows that the following care components reduce the incidence of surgical site infection: appropriate use of prophylactic antibiotics; appropriate hair removal; controlled postoperative serum glucose for cardiac surgery patients; and immediate postoperative normothermia for colorectal surgery patients. These components, if implemented reliably, can drastically reduce the incidence of surgical site infection, resulting in the nearly complete elimination of preventable surgical site infection in many cases.

Where Are We Now?

A medical record review of 34,133 charts performed under the auspices of CMS demonstrated significant opportunity for improvement in surgical site prevention.³ In the area of appropriate antibiotic use, the medical record review found the following:

- Appropriate antibiotic selection occurred in 92.6% of cases;
 - Antibiotics were given within one hour of incision time to 55.7% of patients;
- and

- Prophylactic antibiotics were discontinued within 24 hours of surgery end time for only 40.7% of patients.

These performance levels existed even after these three measures had been generally accepted for several years and had been the focus of many improvement collaboratives, nationally and at the state level.

Recent data from the Surgical Care Improvement Project (SCIP) (September 2010) indicate that performance has improved considerably and, for some measures, has reached or exceeded the 2013 proposed target of 95% adherence to process measures to prevent SSI. Continued focus on these measures will be necessary and important in sustaining this improvement over time.

1 Kirby JP, Mazuski JE. *Surg Clin North Am.* April 2009;89(2):365-389.

2 Kirkland KB, Briggs JP, Trivette SL, Wilkinson WE, et al. The impact of surgical-site infections in the 1990s: attributable mortality, excess length of hospitalization and extra costs. *Infect Control Hosp Epidemiology.* 1999;20:725.

3 Bratzler DW, Houck PM, et al. *Arch Surg.* 2005;140:174-182.

SCIP Data 4

	FY06	FY07	FY08	FY09
Antibiotic 1 hour prior to incision	83%	87%	91%	96%
Appropriate antibiotic administered	n/a	92%	95%	98%
Antibiotic discontinued	74%	80%	87%	92%
Glucose control for cardiac surgery	n/a	n/a	89%	92%
Appropriate hair removal	n/a	n/a	97%	99%

A major national effort has been made to further improve compliance with SSI prevention measures through their inclusion in SCIP. The 5 Million Lives Campaign intervention was aligned with this initiative.

A recent Compendium of Strategies to Prevent Healthcare-Associated Infections in Acute Care Hospitals published by SHEA-IDSA5 (in partnership with the Joint Commission, the Association for Professionals in Infection Control and Epidemiology (APIC), and the American Hospital Association (AHA)) emphasizes the importance of reducing these infections and includes guidelines of practice recommendations to address them.⁶

General Considerations for Improvement in SSI

Any improvement process should be driven by leadership, with a commitment to providing adequate resources and attention to the initiative. It is also imperative to involve a multidisciplinary team in the surgical site infection improvement process. Successful teams set clear aims for their work, establish baseline measurements of performance, regularly measure and study the results of their work, and test various process and systems changes over a variety of conditions in order to find the ones that lead to improvement in their particular setting.

4	Hospital	Compare	Hospital	Quality	Initiatives.
	http://www.cms.gov/HospitalQualityInits/11_HospitalCompare.asp .				Updated August 8, 2011.
	Accessed November 7, 2011.				
5	Compendium	of	Strategies	to	Prevent HAIs.
	http://www.shea-online.org/about/compendium.cfm .				Accessed November 7, 2011.
6	Yokoe DS, Mermel LA, Classen, D, et al. A compendium of strategies to prevent healthcare-associated infections in acute care hospitals. <i>Infect Control Hosp Epidemiol</i> . 2008;29:S12-S21.				

SSI Prevention: Four Components of Care

1. Appropriate Use of Prophylactic Antibiotics

For the purposes of the 5 Million Lives Campaign, the antibiotic process measures are these:

- Prophylactic antibiotic received within 1 hour prior to surgical incision*
- Prophylactic antibiotic selection for surgical patients consistent with national guidelines (as defined in JC/CMS Specification Manual and SCIP for Measure SCIP-Inf-2)
- Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac patients)

It is worth noting that these measures apply to antibiotics administered for SSI prophylaxis only.

The definition of the measures in SCIP excludes patients who are already receiving antibiotics for other reasons. It often is not necessary to administer an additional antibiotic or dose in such cases, as this only leads to unnecessary administrations which should be avoided.

**Due to the longer infusion time required for Vancomycin, it is acceptable to start this antibiotic (e.g., when indicated because of beta-lactam allergy or high prevalence of MRSA) within 2 hours prior to incision.*

What changes can we make that will result in improvement?

Hundreds of hospital teams across the United States have developed and tested process and systems changes that allowed them to improve performance on the antibiotic use measures. Some of these changes are:

- Use preprinted or computerized standing orders specifying antibiotic, timing, dose, and discontinuation.

- Develop pharmacist- and nurse-driven protocols that include preoperative antibiotic selection and dosing based on surgical type and patient-specific criteria (age, weight, allergies, renal clearance, etc.).
- Change operating room drug stocks to include only standard doses and standard drugs, reflecting national guidelines.
- Assign dosing responsibilities to anesthesia or designated nurse (e.g., pre-op holding or circulator) to improve timeliness.
- Involve pharmacy, infection control, and infectious disease staff to ensure appropriate timing, selection, and duration.
- Verify administration time during —time-out¹¹ or pre-procedural briefing so action can be taken if not administered.

2. Appropriate Hair Removal

For many years, it has been known that the use of razors prior to surgery increases the incidence of wound infection when compared to clipping, depilatory use, or no hair removal at all.⁷ Razors can cause small cuts and nicks to skin, many of which may be microscopic and not visible to the human eye. However, many teams working on this measure find that the use of razors in their own institutions can range from zero to nearly 100 percent.

Hair removal may not be necessary for many procedures, yet has been —carried over¹¹ from years ago when surgical patients commonly received extensive pre-op shaving.

When hair must be removed to safely perform the procedure, it should never occur with a razor. It is preferable to use clippers rather than shaving with a razor as this results in fewer surgical site infections.⁸

The use of clippers has been found to be the best method in many hospitals, as depilatory creams can cause skin reactions. Staff must be trained in the proper use of clippers because an untrained user can damage the skin. If hair must be

removed preoperatively, it is generally recommended that this not occur in the operating room itself, as loose hairs are difficult to control.

What changes can we make that will result in improvement?

Hundreds of hospital teams across the United States have developed and tested process and systems changes that allowed them to improve performance on the appropriate hair removal measure. Some of these changes are:

- Ensure adequate supply of clippers and train staff in proper use.
- Use reminders (signs, posters).
- Educate patients not to self-shave preoperatively.
- Remove all razors from the entire hospital.
- Work with the purchasing department so that razors are no longer purchased by the hospital.

7 Seropian. *Am J Surg*. 1971;121:251.

8 Tanner J, Woodings D, Moncaster K. Preoperative hair removal to reduce surgical site infection. *Cochrane Database of Systematic Reviews* 2006, Issue 3. Art. No.: CD004122. DOI: 10.1002/14651858.CD004122.pub3

3. Controlled Postoperative Serum Glucose in Cardiac Surgery *,**

Review of medical literature shows that the degree of hyperglycemia in the postoperative period was correlated with the rate of SSI in patients undergoing major cardiac surgery.⁹ Glucose control postoperatively was focused on the cardiac surgical population during the Campaign, based on the literature and alignment with SCIP. Future studies of the effectiveness of glucose control in other surgical populations may be forthcoming; however, literature to date links this measure with SSI prevention only in the cardiac surgical population. Other articles

have demonstrated that stringent glucose control in surgical intensive care unit patients reduces mortality.¹⁰

**NOTE that, for this effort, “glucose control” is defined as serum glucose levels below 200 mg/dl, collected at or closest to 6:00 AM on each of the first two postoperative days.*

***NOTE that tight glycemic control (e.g., using an insulin drip) is often performed in an intensive care setting or equivalent for safety.*

What changes can we make that will result in improvement?

Hospital teams across the United States are developing and testing process and systems changes to improve performance on the postoperative glucose control measure. Some of these changes are:

- Implement one standard glucose control protocol for cardiac surgery.
- Regularly check preoperative blood glucose levels on all patients to identify hyperglycemia; this is best done early enough that assessment of risk can be completed and treatment initiated if appropriate.
- Assign responsibility and accountability for blood glucose monitoring and control.

9 Latham. *Inf Contr Hosp Epidemiol.* 2001;22:607; Dellinger. *Inf Contr Hosp Epidemiol.* 2001;22:604.

10 Van den Berghe. *NEJM.* 2001;345:1359.

4. Immediate Postoperative Normothermia in Colorectal Surgery*

The medical literature indicates that patients undergoing colorectal surgery have a decreased risk of SSI if they are not allowed to become hypothermic during the perioperative period.¹¹

Anesthesia, anxiety, wet skin preparations, and skin exposure in cold operating rooms can cause patients to become clinically hypothermic during surgery. In the Campaigns and SCIP, focus was directed at colorectal surgery patients based on literature linking them to risk for SSI. However, there is evidence to show that preventing hypothermia is beneficial in reducing other complications, and it clearly is more comfortable for patients.^{12,13,14,15,16}

**NOTE that this component of care does not pertain to those patients for whom therapeutic hypothermia is being used (e.g., hypothermic cardioplegia).*

What changes can we make that will result in improvement?

Hundreds of hospital teams across the United States have developed and tested process and systems changes that allowed them to improve performance on the normothermia measure. Some of these changes are:

- Prevent hypothermia at all phases of the surgical process.
- Use warmed forced-air blankets preoperatively, during surgery, and in PACU.
- Use warmed fluids for IVs and flushes in surgical sites and openings.
- Use warming blankets under patients on the operating table.
- Use hats and booties on patients perioperatively.
- Adjust engineering controls so that operating rooms and patient areas are not permitted to become excessively cold overnight, when many rooms are closed.
- Measure temperature with a standard type of thermometer.

11 Melling. *Lancet*. 2001;358:876.

12 Kurz A, Sessler DI, Lenhardt R. Perioperative normothermia to reduce the incidence of surgical-wound infection and shorten hospitalization. Study of Wound Infection and Temperature Group. *N Engl J Med*. 1996;334:1209-1215.

13 Mahoney CB, Odom J. Maintaining intraoperative normothermia: A meta-analysis of outcomes with costs. *AANA J*. 1999;67:155-163.

- 14 Doufas AG. Consequences of inadvertent perioperative hypothermia. *Best Pract Res Clin Anaesthesiol.* 2003;17:535-549.
- 15 Melling AC, et al. Effects of preoperative warming on the incidence of wound infection after clean surgery: A randomized controlled trial. *Lancet.* 2001;358:876-880.
- 16 Sessler DI, Akca O. Nonpharmacological prevention of surgical wound infections. *Clin Infect Dis.* 2002;35:1397-1404.

Additional SCIP Changes in Care

Beta Blockers for Patients on Beta Blockers Prior to Admission

Much has been written about the use of beta blockers and beta blockade in surgical patients, including non-cardiac surgery, as prevention for intra-operative and postoperative cardiac events.

Published studies show conflicting results, and there is lack of consensus about the appropriateness of beta blockers for some types of patients. A trial presented at the American Heart Association Annual Meeting (POISE Trial) suggested that acute administration of beta blockers beginning the morning of surgery and continued postoperatively in beta-blocker-naïve patients was associated with a reduction in non-fatal myocardial infarction but at an increased risk of stroke and all-cause mortality.¹⁷

However, these results do not apply to the current SCIP measure of continuation of beta blockers in those patients already taking these agents. One thing remains universally agreed upon: **patients on beta blockers preoperatively should be continued on beta blockers postoperatively.**

The American College of Cardiology/American Heart Association Task Force on Practice Guidelines notes, —Beta blockers should be continued in patients undergoing surgery who are receiving beta blockers to treat angina, symptomatic arrhythmias, hypertension, or other ACC/AHA Class I guideline indications. ||¹⁸

Reliable systems should be established to ensure that these patients have their beta blockers continued during the transition from preoperative to postoperative care.

Transition points always carry the risk of inadvertent error. In the postoperative setting, it is not always clear who will be responsible for ordering preoperative medications: surgeons may prefer that a primary care physician (PCP) or internist address these medications, but the PCP may not see the patient in the hospital, especially if the surgical case is uncomplicated and length of stay is short; anesthesiologists may not be writing any postoperative orders at all; hospitalists may not exist in the organization or may not see surgical patients. These types of circumstances may lead to patients not receiving their beta blockers postoperatively and then experiencing withdrawal, which can result in harm. In a study of 140 patients who received beta blockers preoperatively, eight patients had their beta blockers discontinued postoperatively and mortality was 50%, compared to mortality of 1.5% in the other 132 patients who had beta blockers continued (odds ratio 65.0, $P < .001$).¹⁹ Hoeks and colleagues²⁰ studied 711 consecutive peripheral vascular surgery patients, and beta blocker withdrawal was associated with an increased risk of one-year mortality compared to non-users (HR=2.7; 95% CI=1.2-5.9).

A patient on beta blockers prior to admission is defined as one receiving beta blockers for 24 hours prior to incision.

17 <http://www.americanheart.org/presenter.jhtml?identifier=3051716>. Accessed February 18, 2008.

18 ACC/AHA Practice Guidelines. *JACC*. 2006;47:11;2342-2355.

19 Shammash JB, Trost JC, et al. *Am Heart J*. 2001;141(1):148-153.

20 Hoeks SE, Scholte Op Reimer WJ, van Urk H, et al. *Eur J Vasc Endovasc Surg*. 2006.

What changes can we make that will result in improvement?

Hospital teams across the United States have developed and tested process and systems changes that have allowed them to improve performance on beta blocker measures. Some of these changes are:

- Identify patients preoperatively who are on beta blockers to ensure that they are continued postoperatively.
- Develop standard postoperative order sets or automatic protocols that include provision of beta blockers for patients receiving beta blockers preoperatively.
- Designate responsibility for postoperative ordering of preoperative medications.
- Implement medication reconciliation.

Educate patients preoperatively about the importance of continuing beta blockers postoperatively and informing the surgeon and anesthesiologist that they take these medications.

Venous Thromboembolism (VTE) Prophylaxis

Deep vein thrombosis (DVT) is estimated to occur in 10% to 40% of general surgical patients when prophylaxis is not provided. Surgical patients are at increased risk due to stasis in the operating room and postoperatively due to difficulty ambulating from pain, effects of anesthesia, and pain-relieving agents. This can result in a pulmonary embolism (PE) in some cases and can be fatal, sometimes instantly. In a study cited by the American College of Chest Physicians (ACCP), autopsies of surgical patients who died within 30 days postoperatively revealed that 32% had a PE and that it was the cause of death for most.²¹

ACCP has published guidelines for VTE prophylaxis in surgical patients, based on surgery type. ACCP recommends routine prophylaxis for all patients in the target group; signs and symptoms of DVT in early stages are unreliable for preventing significant events. Adherence to these guidelines is the basis of the SCIP measures in this area.

²¹ Lindblad B, Eriksson A, Bergqvist D. *Br J Surg*. 1991;78:849-852.

What changes can we make that will result in improvement?

Hospital teams across the United States have developed and tested process and systems changes that have allowed them to improve performance on the VTE prophylaxis measure. Some of these changes are:

- Develop standard order sets for prophylaxis.
- Develop protocols for providing prophylaxis automatically, based on surgical procedure.
- Provide education and training for staff on the importance of VTE prophylaxis.
- Educate patients preoperatively about the prophylaxis they will receive and steps they can take to reduce risk.

Ventilator-Associated Pneumonia Prevention

According to SCIP, —postoperative pneumonia occurs in 9% to 40% of surgical patients and has an associated mortality of 30% to 45%.^{22,23} While not all surgical patients receive postoperative mechanical ventilation, those who do are at risk for one of the most serious types of pneumonia: ventilator-associated pneumonia (VAP).

What changes can we make that will result in improvement?

Hospitals seeking to aggressively reduce surgical complications should consider using the Ventilator Bundle for all surgical patients receiving postoperative mechanical ventilation, particularly those ventilated for more than 24 hours. A complete How-to Guide: Prevent Ventilator-Associated Pneumonia is available.

22 Brooks-Brunn JA. Predictors of postoperative pulmonary complications following abdominal surgery. *Chest*.1997;111:564-71.

Using the Model for Improvement

In order to move this work forward, IHI recommends using the Model for Improvement. Developed by Associates in Process Improvement, the Model for Improvement is a simple yet powerful tool for accelerating improvement that has been used successfully by hundreds of health care organizations to improve many different health care processes and outcomes.

The model has two parts:

- Three fundamental questions that guide improvement teams to 1) set clear aims, 2) establish measures that will tell if changes are leading to improvement, and 3) identify changes that are likely to lead to improvement.
- The Plan-Do-Study-Act (PDSA) cycle to conduct small-scale tests of change in real work settings — by planning a test, trying it, observing the results, and acting on what is learned. This is the scientific method, used for action-oriented learning.

Implementation: After testing a change on a small scale, learning from each test, and refining the change through several PDSA cycles, the team can implement the change on a broader scale — for example, for an entire pilot population or on an entire unit.

Spread: After successful implementation of a change or package of changes for a pilot population or an entire unit, the team can spread the changes to other parts of the organization or to other organizations.

You can learn more about the Model for Improvement at www.ihl.org



Project: SSI - Prophylactic Antibiotic within One Hour before Incision

Objective for this PDSA Cycle: Test administration of antibiotic by anesthesiologists.

Plan:

Questions: Will anesthesiologists agree to administer the antibiotic and document the time?

Predictions: The anesthesiologists will agree. Documentation location may need to be clarified for consistent practice.

Plan for change or test – who, what, when, where:

Get an anesthesiologist to volunteer to administer and document one antibiotic dose for first case on Tuesday.

Plan for collection of data – who, what, when, where:

- Nurse will record observations and any issues that arise.
- Anesthesiologist will document administration time on preoperative checklist.
- Debrief with anesthesiologist after the surgery is complete.

Do:

Carry out the change or test. Collect data and begin analysis.

- Conducted the test on the first surgery on Tuesday morning.
- The anesthesiologist became frustrated because she did not have the pre-op checklist at administration time because the circulating nurse was using it.

Study:

Complete analysis of data.

- Debrief: Discuss whether the administration time can be documented on the

anesthesia record instead of on the checklist. The anesthesiologist is willing to try the test again tomorrow.

How did or didn't the results of this cycle agree with the predictions that we made earlier?

Documentation form currently in use is not ideal for use by anesthesiologists if they administer the dose.

- Summarize the new knowledge we gained by this cycle: May need to revise checklist and anesthesia record if tests are successful, so that documentation of administration time is always in the same place.

Act:

List actions we will take as a result of this cycle: Repeat this test tomorrow after drafting a sample revision to anesthesia record. Plan for the next cycle (adapt change, another test, implementation cycle): Run a second PDSA cycle tomorrow for three scheduled surgeries.

Forming the Team

No single person can create system-level improvements alone. First, it is crucial to have the active support of leadership in this work. The leadership must make patient safety and quality of care strategic priorities in order for any surgical care improvement team to be successful.

Once leadership has publicly given recognition and support (dollars, person-time) to the program, the improvement team can be quite small. Successful teams include a physician (either a surgeon, anesthesiologist, or both), an operating room nurse, and someone from the quality department.

Each hospital will have its own methods for selecting a core team. The team should use the Model for Improvement to conduct small-scale, rapid tests of the ideas for improvement over various conditions in a pilot surgical population. The team

should also track performance on a set of measures designed to help them see if the changes they are making are leading to improvement, and regularly report these measures back to leadership.

Measurement

See Appendix A for specific information regarding the recommended process and outcomes measures for surgical site infection prevention.

The recommended outcome measure is —Percent of Clean Surgery Patients with Surgical Infection¹¹ (i.e., surgical site infections within 30 days of surgery for patients with Class I / Clean wounds, as defined by CDC and NSQIP for wound classification). If you are just starting this work, this may be a good measure to begin tracking. We are not distinguishing as to whether this is superficial infections only, or also includes deep incision and organ space infections; this should be decided locally for your organization. As your work progresses and you are ready for advanced measures on this topic, consider measures that address the different types of SSIs as well as the other classes of wounds, similar to the data being collected in the National Surgical Quality Improvement Program at the American College of Surgeons.

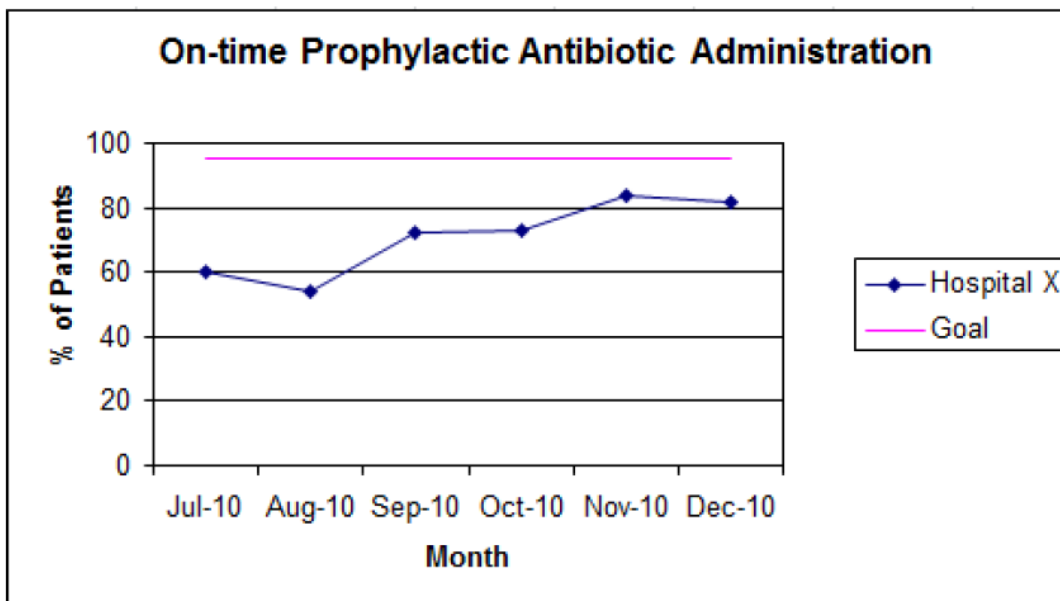
For each process measure, obtain the data via medical record review. (Follow the links in Appendix A for details about data collection.) The process measures recommended by the Campaigns are identical to those being used in CMS's current Surgical Infection Prevention program, the Joint Commission's current core measure set, and SCIP. Using run charts helps make change over time visible to the team and to the leadership.

Run Charts

Improvement takes place over time. Determining if improvement has really happened and if it is lasting requires observing patterns over time. Run charts are graphs of data over time and are one of the single most important tools in performance improvement.

Using run charts has a variety of benefits:

- They help improvement teams formulate aims by depicting how well (or poorly) a process is performing.
- They help in determining when changes are truly improvements by displaying a pattern of data that you can observe as you make changes.
- As you work on improvement, they provide information about the value of particular changes.
- Run chart example – first test of change:



Teams may elect to work on any or all of the four care components: antibiotic use, hair removal, glucose control, and normothermia. A first test of change should involve a very small sample size (typically one patient) and should be described

ahead of time in a Plan-Do-Study-Act format so that the team can easily predict what they think will happen, observe the results, learn from them, and continue to the next test.

Example: Administration of preoperative dose of antibiotic

- The team decides to test having the anesthesiologist administer the preoperative dose of prophylactic antibiotic and document the administration time. They identify an anesthesiologist who supports the idea, and let the anesthesiologist know that they will test this with one case. On their PDSA form, they predict that the surgeon will agree to administer the dose but that documentation may need to be clarified. They then conduct the test. They note that the anesthesiologist becomes frustrated because s/he cannot access the preoperative checklist used for documentation of administration time because it is in use by the circulating nurse. The team's study of the data indicates that they should repeat this test, after first developing an alternative documentation location that will be accessible to the anesthesiologist at the time of administration.

Ideally, teams will conduct multiple small tests of change simultaneously across all four components of care. This simultaneous testing usually begins after the first few tests are completed and the team feels comfortable and confident in the process.

Implementation and Spread

For surgical site infection, teams will usually choose to begin their improvement process by working with a —pilot|| population. This pilot population may be the hip- and knee-replacement patients, for example, or cardiac operations, or gynecologic procedures, etc. It is possible to include the universe of surgical

patients in the pilot population, if that number is small (fewer than 50 cases per month). We recommend including at least 50 cases per month in the pilot population in order to increase the ability to measure and detect improvement.

In order to maximize the reduction in overall hospital mortality related to surgical site infections, however, hospitals must spread improvements begun in a pilot population to the universe of surgical populations. Organizations that successfully spread improvements use an organized, structured method in planning and implementing spread across populations, units, or facilities.

You can find information about planning, tracking, and optimizing spread at www.ihl.org. (See IHI's Innovation Series white paper, "A Framework for Spread: From Local Improvements to System-Wide Change")

Barriers

Teams working on preventing surgical site infection have learned a great deal about barriers to improvement and how to overcome them. Some common challenges and solutions are:

- Lack of support from leadership
Solution: Use opinion leaders (physicians) and data and if possible; a business case for the project may help to win leadership support.
- Uneven physician acceptance of new practices
Solution: Use physician opinion leaders, review the medical literature, and feed back data on a surgeon-specific level. Remember that physicians may fall anywhere on the "Adoption of Innovations" curve; work first with your early adopters and use their stories to convince the majority.

Tips and Tricks

More than 3,000 hospitals across the US have been working hard to implement the Campaign interventions. Here are some of the —tips and tricks‖ for successful testing and implementing of each intervention that we have gathered from our site visits to Campaign hospitals, our Campaign calls, and our Discussion Groups at www.ihl.org.

- Set a narrower range internally for timing of the preoperative antibiotic dose, e.g., 5 to 50 minutes prior to incision. This helps account for clocks not in synchrony and allows a small buffer.
- Use 36.5 degrees Celsius as the intervention point for temperature; waiting until 36 degrees is usually too late to prevent hypothermia below that level.
- Measure pre-op blood glucose early enough so that if it is unexpectedly high, a plan of action can be initiated.
- Schedule the times for post-op doses of prophylactic antibiotics in the OR, based on the time incision is closed, to ensure completion within 24 hours (don't use standard dosing times).
- Measure the SSI interventions as an all-or-nothing measure for each patient.
- Approach the SSI interventions like —mini-bundles‖ for each phase: pre-op, intra-op, and post-op. Hold each area accountable for their bundle.
 - Maintain a reasonable temperature in the OR – not too cold for patients, but not too warm for staff. High 60s Fahrenheit seems to be ideal.
- Don't allow operating rooms to get excessively cold overnight when closed.

Frequently Asked Questions

Surgical Site Infections

Our surgeons are asking, “If there is no data that what I am doing—e.g., shaving just before surgery—is dangerous, why should I change?” I have no evidence-based medicine with which to answer them.

There is ample evidence that shaving prior to a surgical procedure is associated with more wound infections than removing hair with clippers or not removing hair at all. The papers that support this conclusion are sound. You can challenge the studies as not specifically looking at shaving immediately prior to surgery because that study has not yet been done, as most patients are not prepared for surgery that way. There is nearly always a time gap between the shave prep and the incision; this likely varies greatly from institution to institution. It can be inferred from the literature that the time interval between the shaving and the incision is likely related to the wound infection rate. That interval in many cases is not absolutely controllable; cases get delayed or cancelled, putting those patients into a time range (from prep to incision) that we know scientifically is associated with more wound infections.

Further, there is no evidence that shaving immediately prior to surgery is a safe thing to do. There is no evidence that shaving with a razor at any time prior to surgery is ever associated with a lower rate of any type of complication. Why would you take a chance, in this unstudied area, with the patient’s outcome?

Questions have come up in our organization regarding serum glucose. Can you help clarify?

In the glucose control measure for cardiac surgery patients, the goal is to include the “serum” glucose level as measured at 6 AM (or as close as possible to this time) on post-op days 1 and 2.

The word —serum|| has caused some confusion; it has been interpreted as serum analyzed by the lab only (not finger sticks). We have clarified the definition with colleagues at SCIP.

Glucose values for this measure may be obtained from the following:

- Blood sugar
- Fasting glucose
- Finger stick glucose
- Glucometer results
- Glucose
- Non-fasting glucose
- Random glucose
- Serum glucose

What is the time frame for defining post-op wound infections for this measure? Is it infections documented while in the hospital, or does it extend post-discharge?

Most places are measuring SSI within 30 days and, in general, that has been our recommendation.

Most inpatient stays are so short that we must consider the time after discharge, although surveillance is a real challenge.

The interventions we used in the 5 Million Lives Campaign contribute mostly to preventing infections within 30 days.

Is anyone looking at communication and handoffs relative to SSI prevention, specifically at incorporating Team Resource Management constructs such as briefings/debriefings and handoff tools in helping to ensure that all interventions have been completed?

A number of hospitals have built the SSI prevention items into their pre-procedural briefing. For example, during the briefing one of the items verified is

whether the prophylactic antibiotic has been administered. If it has not, this step provides an opportunity to mitigate.

A Fact Sheet for Patients and Their Family Members

Most patients who have surgery do well, but sometimes patients get infections. This happens to about 3 out of 100 patients who have surgery. Infections after surgery can lead to other problems.

Sometimes, patients have to stay longer in the hospital. Rarely, patients die from infections.

Patients and their family members can help lower the risk of infection after surgery. Here are some ways:

Days or weeks before surgery:

Meet with your surgeon.

- Bring an up-to-date list of all the medications you take. Talk with your surgeon about why you take each medication and how it helps.
- Let the surgeon know if you are allergic to any medication and what happens when you take it.
- Tell the surgeon if you have diabetes or high blood sugar, or if family members do.

Talk about ways to lower your risk of getting an infection. This may include taking antibiotic medicines.

The day or night before surgery:

Take extra good care of your body.

- Do not shave near where you will have surgery. Shaving can irritate your skin, which may lead to infection. If you are a man who shaves your face every day, ask your surgeon if it is okay to do so.
- Keep warm. This means wearing warm clothes or wrapping up in blankets when you go to the hospital. In cold weather, it also means heating up the car before you get in.

Keeping warm before surgery lowers your chance of getting an infection.

At the time of surgery:

- Tell the anesthesiologist (doctor or nurse who puts you to sleep for surgery) about all the medications you take. A good way to do this is to bring a written, up-to-date medication list with you.
- Let the anesthesiologist know if you have diabetes or high blood sugar, or if family members do. People with high blood sugar have a greater chance of getting infections after surgery.
- Speak up if someone tries to shave you with a razor before surgery. Ask why you need to be shaved and talk with your surgeon if you have any concerns.
- Ask for blankets or other ways to stay warm while you wait for surgery. Find out how you will be kept warm during and after surgery. Ask for extra blankets if you feel cold.
- Ask if you will get antibiotic medicine. If so, find out how many doses you will get. Most people receive only one dose before surgery and are on antibiotics for just one day after surgery, as taking too much can lead to other problems.

Appendix A: Recommended Intervention-Level Measures

The following measures are relevant for this intervention. We recommend that you use some or all of them, as appropriate, to track the progress of your work in this area. In selecting your measures, we offer the following advice:

- ⊙ Whenever possible, use measures you are already collecting for other programs.
- ⊙ Evaluate your choice of measures in terms of the usefulness of the results they provide and the resources required to obtain those results; try to maximize the former while minimizing the latter.
- ⊙ Try to include both process and outcome measures in your measurement scheme.
- ⊙ You may use measures not listed here, and, similarly, you may modify the measures described below to make them more appropriate and/or useful to your particular setting; however, be aware that modifying measures may limit the comparability of your results to others'. (Note that hospitals using different or modified measures should not submit those measure data to IHI.)
- ⊙ Remember that posting your measure results within your hospital is a great way to keep your teams motivated and aware of progress. Try to include measures that your team will find meaningful, and that they would be excited to see.

Process Measures

Note that all of the process measures are the same as those used in the 100,000 Lives Campaign; we have simply changed our policy of creating Measure Information Forms (MIFs) for measures which have already been defined by others, and instead now link directly to the “owner’s” measure definition.

Alignment with Other Measure Sets

Measure Name	JC	CMS	SCIP	NQF	CDC
Percent of Surgical Patients with Prophylactic Antibiotic Received within One Hour Prior to Surgical Incision – Overall Rate	√1	√2	√3	√4	
Percent of Surgical Patients with Appropriate Selection of Prophylactic Antibiotic – Overall Rate	√1	√2	√3	√4	
Percent of Surgical Patients with Appropriate Prophylactic Antibiotic Discontinuation – Overall Rate	√1	√2	√3	√4	
Percent of Major Cardiac Surgical Patients with Controlled Post Operative Serum Glucose	√1	√2	√3		
Percent of Surgical Patients with Appropriate Hair Removal	√1	√2	√3		
Percent of Colorectal Surgical Patients with Normothermia in PACU	√1	√2	√3		
Percent of Clean Surgery Patients with Surgical Infection					√5
Surgery Patients on Beta Blocker Therapy Prior to Admission Who Received a Beta Blocker During the Perioperative Period	√1	√2	√3		
Surgery Patients with Recommended Venous Thromboembolism Prophylaxis Ordered	√1	√2	√3		
Surgery Patients Who Received Appropriate Venous Thromboembolism Prophylaxis Within 24 Hours Prior to Surgery to 24 Hours After Surgery	√1	√2	√3		

1 Matches a measure in the Joint Commission (JC) National Hospital Quality Measures SCIP Core Measure Set

2 Matches a measure in the CMS SCIP measure set

3 Matches a measure in the SCIP measure set

4 This measure is endorsed by the NQF

5 The definitions of —clean surgery patient¹¹ and —surgical infection¹² used in this measure are the same as the CDC’s National Healthcare Safety Network (NHSN) Surgical Site Infection Event definitions, which can be found here.

