



Making the **safety** of patients
everyone's highest **priority**

The 'How to Guide' for
**Reducing Harm in
Critical Care**

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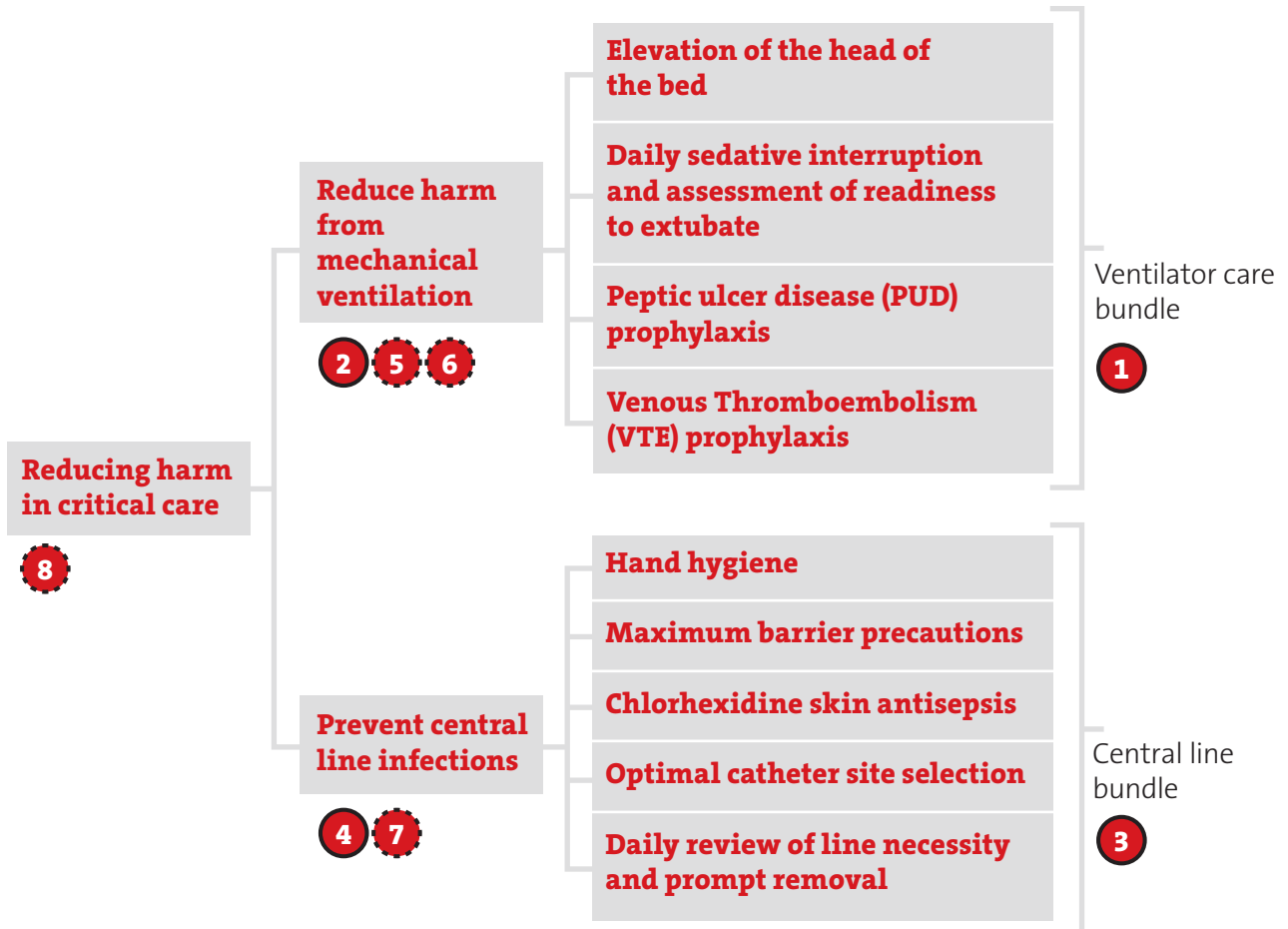
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General Introduction

All over the world, including in the UK, health care workers are proving that patient safety can be greatly improved and many complications or harm events that were previously considered unavoidable actually are avoidable. They are in fact, redefining what is acceptable in terms of patient safety.

The purpose of each of the Patient Safety First interventions is to provide you with a focus on which to begin or progress improvements in patient safety in your organisation. Each proposed intervention has an underpinning evidence base that identifies the need for change and how its elements can help you on a journey that will make a real impact on rates of patient harm and death.

The proposed elements, suggested changes and associated measures discussed in this document are not exhaustive; rather, a basis on which to start making a difference in the given area. It also provides a sound methodical approach that can be applied repeatedly in other improvement efforts you may wish to initiate.

The content of this guide will never be considered to be final. Regular reviews will be conducted to update it with new evidence, initiatives and key learning from organisations participating in the Patient Safety First campaign. Your suggestions for improvement and case studies are welcomed; please share your learning with your local campaign contact or contact us direct via the Patient Safety First website www.patientsafetyfirst.nhs.uk.

Reducing Harm in Critical Care

Background

This document is aimed at team members involved in implementing changes to reduce harm in critical care. It may also provide a useful overview for the following:

- Relevant service managers
- Senior managers/executives supporting the work and monitoring its progress
- Service improvement personnel who may be required to provide improvement or change management expertise in relation to the work.

The evidence base for the various elements of the Ventilator Care and Central Line Bundles have not been included in this document purely for the purpose of conciseness and an attempt to focus on the 'how-to'. This information can be found in the accompanying Campaign documents:

The summaries:

- Reducing Harm in Critical Care: Reducing Harm from Mechanical Ventilation
- Reducing Harm in Critical Care: Prevent Central Line Infections, and
- Critical Care References and Bibliography.

All available from the Patient Safety First website www.patientsafetyfirst.nhs.uk.

Reducing Harm from Mechanical Ventilation

Ventilated patients are at high risk of several serious complications: ventilator associated pneumonia (VAP), venous thromboembolism (VTE), and stress-induced gastrointestinal bleeding.

VAP is a nosocomial lung infection that occurs in patients receiving mechanical ventilation and for whom the infection was not the reason for ventilation, i.e. the infection commenced after ventilation. Pneumonia is considered as ventilator associated if the patient was intubated and ventilated at the time or within 48 hours before the onset of infection. Preventing pneumonia of any kind is certainly a laudable goal. However, there are reasons to be particularly concerned about the impact of pneumonia associated with ventilator use.

The ventilator bundle was designed as part of an overall strategy to improve the care of ventilated patients. The original intent was not to reduce VAP rates, but rather to provide best care for patients on ventilators. It is clear that ventilated patients require prophylaxis to prevent venous thromboembolism, stress ulceration and dangerous gastrointestinal bleeding or other complications based on solid evidence.

Prevent Central Line Infections

Central venous catheters (CVCs) are used increasingly 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 and haemodynamic changes and organ dysfunction (severe sepsis) may ensue, possibly leading to death.

It is estimated that approximately 200,000 central venous lines are inserted in the UK each year of these approximately 6.2% (or 12,400 cases) result in a central line related sepsis.

A 2006 prevalence survey found that 42.3% of bloodstream infections in England are central line-related. In 2000, the National Audit Office (NAO) estimated the additional cost of a bloodstream infection to be £6,209 per patient. The 2000 NAO report noted that 13% of the hospitals in its study had been using catheter care guidelines and that this had reduced the incidence of healthcare associated infection (HCAI). However, a follow-up report in 2004 noted that 10% of responding trusts had still not taken up the guidelines.

The Intensive Care National Audit & Research Centre (ICNARC) has recognised that central line related bloodstream infections are an issue which needs to be addressed, and have begun collecting data on the exact scale of the problem. Central line related bloodstream infections appear to be prevalent but they are also largely preventable.

An approach which has been shown to work was highlighted within the Lord Ara Darzi's report *High Quality Care for All*, 2008. This promoted a project which used a co-ordinated approach to reducing central line infections in adult Intensive Care Units (ICUs). The Patient Safety First Campaign has therefore based this 'how to guide' on this best practice model. *High Quality Care for All* stated that the NPSA would lead on this work with an initiative to replicate the Michigan study. All adult ICUs will be invited to join the 'Matching Michigan'* initiative from April 2009. Therefore, if you choose this intervention as part of the Patient Safety First Campaign, in addition to resources and support from the campaign, you will also be supported through a collaborative network set up by the NPSA to help you implement the bundle to reduce central line infections in your ICU.

**Pronovost, MD et al., 2006, An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU, The New England Journal of Medicine.*

Implementing Care Bundles

Complying with this intervention has two distinct parts, both of which focus on the use of a care bundle to reduce harm in different areas of critical care practice:

- Reducing Harm from Mechanical Ventilation: The Ventilator Care Bundle
- Prevent Central Line Infections: The Central Line Bundle.

What is a care bundle?

Care bundles in general are groupings of best practices with respect to an intervention or a disease process that individually improve care, but crucially, when applied together may result in substantially greater improvement. A bundle is an effort to design a standard approach to delivering these core elements of care. The approach has been most successful when all elements are executed together, an ‘all-or-none’ strategy.

Not all possible therapies are included in a particular bundle, as it is not intended to be a comprehensive list of all care that should be provided. For example, several interventions such as oral care, subglottic suctioning, selective decontamination of the gut, and continuous lateral rotation are not included in the ventilator care bundle but are still considered to be elements of good ventilator care.

Not all bundles are the same. For example the components in one ventilator bundle may differ from those in another. In choosing interventions to apply, a variety of factors must be considered, such as cost, ease of implementation, and demonstrated adherence to the most basic preventative measures in the initial instance, or elements that have a significant impact on morbidity/mortality. Expensive interventions may have dramatic effects when applied; however, equally impressive results may be obtained from less costly and more rudimentary care patterns. Frequently, the question, “Why is such-and-such a therapy not included in a bundle?” is asked and should first be answered by asking whether the fundamentals that are already in the bundle are being executed reliably.

How do I know if a care bundle is being implemented reliably?

Reliable implementation of a bundle, that is, *all of the components* being applied, *all of the time* is shown to be the most successful. Compliance with a bundle can be measured by simple assessment of whether each of the components has been adhered to.

The systems for collection of compliance data are usually developed by the individual units and therefore contain some variation in approach. However, there are several common features. In most units the system is paper based and relies upon the bedside nurse ensuring that a form is completed on a daily basis. It is important to create accepted exclusion criteria for each element, as this helps to identify whether failure to implement is clinical exclusion or non compliance.

Bundle elements ticked are completed, signed if not completed and reasons for exclusion from the bundle recorded. Compliance is ‘all or nothing’ in that patients are only considered compliant if all elements of the bundle have been performed or a reason given for not doing so.

Example of a bundle compliance form

It is not uncommon for an organisation to say “we have already implemented that bundle so this is not a problem for us”. However in some of these cases it has come about as a result of a policy or mandate that has been issued and resultant compliance presumed. Performing a compliance audit can reveal a different picture. In reality full implementation may be inconsistent for a number of reasons such as lack of awareness in some staff or some may not consider some elements of the bundle essential.

	Yes	No	Clinical Exclusion
Component 1	✓		
Component 2		✓	
Component 3			✓
Component 4	✓		

Credit is given if a reason for excluding the bundle or one of its elements is given

Can I implement the bundle but exclude some items?

While this is possible, it is not recommended. In fact, the goal of bundling therapies together is to create a linkage between practices that makes the overall process more effective. Certainly, in terms of monitoring compliance with the ventilator bundle, ‘picking and choosing’ items would be unwise.

Can I add items to the bundle?

Yes, but this should be exercised with caution. Some of the power of a bundle lies in its simplicity which makes the full bundle easy to remember and more likely to be reliably implemented. The bundle should be considered the core set, many other items may be listed separately, for example as a related checklist of good care management.

Implementing the Ventilator Care Bundle

Before progressing further with this document it is recommended that you read the accompanying Campaign document 'The Quick Guide to Implementing Improvement' as it contains background information on:

- The Model for Improvement – a suggested approach to undertaking any improvement activity
- Getting Started – a series of actions to consider working on prior to attempting to implement changes.

This bundle has four key components:

1. Elevation of the head of the bed to between 30 and 45 degrees
2. Daily 'sedative interruption' and daily assessment of readiness to extubate
3. Peptic ulcer disease (PUD) prophylaxis and Venous thromboembolism (VTE) prophylaxis

In addition, good management includes:

- Appropriate humidification of inspired gas
- Appropriate tubing management (replace when visibly soiled or mechanically malfunctioning, routinely replace according to manufacturer's guidance, and prevent condensate from entering patient's airway).

At time of writing (August 2008) NICE/NPSA released further guidance which included:

- Oral antiseptics (for example chlorhexidine) should be included as part of the oral hygiene regimen for all patients who are intubated and receiving mechanical ventilation.

Technical patient safety solutions for ventilator-associated pneumonia in adults
www.nice.org.uk/guidance/index.jsp?action=byID&o=12053.

The Quick Guide to Implementing Improvement

If you have started working through this accompanying document's list in 'Getting Started' you should have a team in place that is committed to implementing the Ventilator Care Bundle. Gather the team together and work through the following questions based on the approach outlined in the section 'The Model for Improvement'.

What are we trying to achieve?

In order to agree your aim you need to understand the current state. Find out if you are already using any of the bundle elements as standard. If you already have the bundle in place, perform an audit to find out your current level of compliance. This helps you to set a realistic timeframe for your goal. An example of an aim statement could be:

We will reduce harm events in ICU by implementing the Ventilator Care Bundle with 95% of ventilated patients within 1 year.

How will we know a change has been an improvement?

Measurement is the only way to know whether a change represents an improvement.

Create your operational definition. It is critical that teams determine some set of criteria by which they will define a VAP in their hospital. Once this has been established, all stakeholders will share a common understanding of what exactly qualifies as a VAP and what does not. Likewise, the team should determine its own exclusion criteria. For example, patients on muscle relaxants being excluded from sedation holds.

Decide what measures will inform you of your progress and how you are going to collect them. There are two measures for this intervention that require reporting to Patient Safety First via the on line extranet site.

- Ventilator Care Bundle compliance
- Days between VAP.

Measure	How to calculate	Guidance
Ventilator Care Bundle compliance	<ul style="list-style-type: none"> • Determine the numerator: the number of ventilated patients in the sample receiving all 4 components of the ventilator bundle • Determine the denominator: the total number of patients reviewed • Calculate the percent compliance with the ventilator bundle by dividing the numerator by the denominator and multiplying the result by 100 	<ul style="list-style-type: none"> • Select ALL ventilated patients in the unit(s) on a randomly selected day each week. Rotate days of the week and shifts • Use daily goals sheet or consultant order sheet as the primary data source or direct observation • Remember this is a YES/NO outcome – only patients receiving all 4 components of the bundle are recorded as compliant • Remember to give credit where a reason for exclusion is documented • Perform the audit weekly but report to the extranet monthly. Aggregate the weekly results by totalling the numerator and denominator separately and entering them onto the extranet. The extranet will perform the relevant calculation.
Days between VAP cases	<ul style="list-style-type: none"> • This measure is a cumulative count of the number of days that have gone by with no VAP being reported. Every time an infection occurs the count is started over again. In this case, we are plotting successes between failures. The longer the run of cumulative successes (days with no VAP occurring) the better 	<ul style="list-style-type: none"> • Whenever events occur that are relatively rare in nature or when a ward or pilot area has sufficiently small numbers of events, the preferred way to go about analysing the data is to plot: (1) successes between failures, or (2) time between failures. Both of these techniques have been used in the Safer Patients Initiative work

An example of a Ventilator Care Bundle audit chart can be seen in *Appendix 1*.

However there are other measures that you could use in addition to inform you of the impact of implementing the bundle.

Measure	How to calculate	Guidance
Average length of stay (ALOS) on mechanical ventilation	<ul style="list-style-type: none"> • Determine the numerator: the total number of ICU mechanical ventilator days during the month • Determine the denominator: The total number of ICU patients on a mechanical ventilator during the month • Calculate the ALOS on mechanical ventilator by dividing the numerator by the denominator 	<ul style="list-style-type: none"> • This measure should not be based on a sample
ICU ALOS	<ul style="list-style-type: none"> • Determine the numerator: The total number of ICU patient days during the month • Determine the denominator: total number of patients discharged from the ICU during the month. • Calculate the ICU ALOS. All patients discharged in a given month should have their length of stays summed up and divided by the number of patients. This is the average for the month 	<ul style="list-style-type: none"> • Collect and report this measure monthly for patients discharged from ICU

Measure	How to calculate	Guidance
VAP rate	<ul style="list-style-type: none"> • Determine the numerator: The total number of VAP cases in the month • Determine the denominator: the total ventilator days in the month • Calculate VAP rate for 1000 ventilator days by dividing the total number of VAPs occurring in the month by the total number of ventilator days in the month. Multiply the result by 1000 	<ul style="list-style-type: none"> • There should be no sampling for this measure. • Report data monthly • Provide numerators and denominators when entering the data • The annotation section should be used to reflect any interventions that were made to reduce the VAP rate

Some teams have preferred to use a sampling approach to assess compliance with the ventilator bundle. For example, some teams use spot checks of compliance three times per week, whereas other teams have chosen daily assessments of compliance at designated times. Regardless of the method, be sure to maintain the standard over time for accurate results.

An example of an audit tool from the *Saving Lives* initiative can be found in *Appendix 2*.

Comparing VAP rates between hospitals. The practice of comparing rates of disease entities or patterns of therapy across institutions is commonly known as ‘benchmarking.’ Benchmarking, while commonly utilised to track performance, may not be a valid method to compare performance between facilities because of differences in patient population, resource availability, or severity of illness.

Fortunately, none of the work required to improve the care of ventilated patients requires a comparison of rates between hospitals. As long as you establish methods in your organisation to determine the patterns and methods of your regular data collection, your results will be consistent over time with respect to your own performance and your own improvement, which is the primary interest.

Any benchmarking should be based on improvement, rather than comparing rates. If you learn of a hospital that has significantly improved, based on data and using the same measure over time, then learn from their work! Even if they are using a different definition from your hospital or treat some different populations, there will still be value in finding out what practices and changes they used to achieve their results.

What changes can we make that will result in an improvement?

Making this initiative fit into the patterns and habits in your hospital is essential. Teams will be most effective if they engage doctors, nurses, physiotherapists and pharmacists to work with them to develop key aspects of the implementation. Where possible, try to fit new actions alongside ones that are already established. This increases the likelihood that they will be remembered and therefore carried out. For example:

- **Include the bundle elements into routine paperwork (such as a daily goals sheet)**
- **Make a spot check of the bundle as part of the daily rounds.** This sends a clear message that this is an important part of the care plan as well as acting as a reminder. With members of the multidisciplinary team present you can also clarify if any patients are excluded from certain elements of the bundle and ensure the reason is documented
- **Post updates to results regularly and prominently.** Enthusiasm for the project will wane over time if clinical staff perceive that the leadership's enthusiasm has diminished. It is essential to regularly update all involved staff in the work on the monthly level of compliance and the monthly change in rates. Not only will this show dedication to the project but when the momentum becomes apparent, clinical staff will be aware of the progress
- **Discourage the tendency to select and try out items that seem easy at the expense of more difficult options also included in the bundle.** Your aim is 100% compliance with every bundle element for every patient; partial compliance is the equivalent of non-compliance. Remember though, to give credit for compliance if a bundle element is not given for clinically appropriate reasons, provided that the discussion with the team occurred and it is clearly documented.

1. Elevation of the head of the bed to between 30 and 45 degrees

- Involve families in the process by educating them about the importance of head-of-the-bed elevation and encourage them to notify clinical personnel if the bed does not appear to be in the proper position
- Create an environment where physiotherapists work collaboratively with nursing to maintain head-of-the-bed elevation
- Use visual cues. Bring a protractor into the ICU to show staff exactly what 45° elevation looks like. Once you have measured 45° for that bed, place a piece of coloured tape on the wall behind and verify compliance during checks. You could also put a line on the wall that can only be seen if the bed is below 30°
- Place a reminder poster on the wall at the head of the patient's bed
- Perform spot checks and present aggregate data for the percent compliance in your ICU to staff visibly and regularly
- Make head-of-the-bed elevation part of a daily goals sheet for each patient
- If you are using an ICU flow sheet (electronic or paper), include a box for documentation of head-of-bed angle (every 4–6 hours, for example).

2. Daily 'sedative interruption' and daily assessment of readiness to extubate

- 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 sedative interruption strategy in your overall plan to wean the patient from the ventilator; if you have a weaning protocol, add sedative interruption
- Consider implementation of an appropriate sedation scale to avoid over-sedation.

3. Peptic ulcer disease (PUD) prophylaxis and Venous thromboembolism (VTE) prophylaxis

- Involve your pharmacists. Pharmacists can help you with a variety of actions relating to the bundle such as helping develop exclusion criteria for the relevant prophylactic medications and providing prompts if these are not administered. Empower pharmacy to review orders for patients in the ICU to ensure that some form of PUD and VTE prophylaxis is in place at all times on ICU patients
- Make PUD and VTE prophylaxis the default. Include as part of your ICU admission order set.

Plan, Do, Study, Act (PDSA)

- Work with one consultant to identify a patient who will receive the bundle
- Work with one nurse willing to carry out the test and ensure they are able to follow the bundle and implement the checklist
- Process feedback and incorporate suggestions for improvement
- Engage in additional PDSA cycles to refine the process and make it more reliable.

Once you have a stand alone process that works:

- Make sure that the approach can be carried over from shift to shift to eliminate gaps in teaching and utilisation
- Once the intervention has been applied to one patient over subsequent shifts, slowly increase the number of patients who receive the bundle.

An example of a PDSA cycle form for the ventilator bundle can be found in *Appendix 3*.

General Questions Relating to the Ventilator Care Bundle

What are the inclusion and exclusion criteria for the Ventilator Care Bundle (for the individual bundle elements)?

No specific exclusion criteria exist, but good clinical judgment should be exercised in conjunction with close attention to the evidence base. Likewise, no specific inclusion criteria are available. Instead, teams interested in improving their performance should develop criteria in conjunction with their clinical staff and apply them uniformly over time. In so doing, teams will have an accurate standard whereby they can measure their own progress in comparison to the only standard that is truly meaningful; their own data.

As an example, some institutions have proposed criteria for excluding patients from various parts of the bundle. One institution excludes patients from interruption of sedation if any of the following criteria apply:

- Open abdominal wound in which fascia is not closed, unless ordered by a doctor
- Intracranial Pressure > 20, unless ordered by a doctor
- Severe O₂ desaturation while on FiO₂ > 90%, unless ordered by a doctor.

Workable inclusion criteria, exclusion criteria, measurement systems, and protocols all require customisation at the local level to be effective. The only key factor in all of these decisions is that the standards, once decided, are adhered to over time.

I am looking for policy/procedures on how to conduct a sedative interruption? Can anyone help me with this?

The best resource to understand the procedure used is the original article:

Kress JP, Pohlman AS, O'Connor MF, Hall JB. Daily interruption of sedative infusions in critically ill patients undergoing mechanical ventilation. N Engl J Med. May 18 2000;342(20):1471-1477.

In the study, an investigator interrupted the sedation each day until the patients were awake and could follow instructions or until they became uncomfortable or agitated and were deemed to require the resumption of sedation. A nurse evaluated the patients each day throughout the period when infusions were stopped until the patients were either awake or uncomfortable and in need of resumed sedation. This nurse immediately contacted a study physician when a patient awakened, at which time the study physician examined the patient and decided whether to resume the infusions. The sedative infusions were started again after the patient was awake or, if agitation prevented successful waking, at half the previous rates and were adjusted according to the need for sedation. For patients receiving muscle relaxants, a slightly modified procedure was used.

Some people use sedation scales to manage over sedation. Is this a reasonable substitute for the interruption of sedation in the bundle?

The use of subjective and objective criteria may be helpful in maintaining the desired level of sedation, despite changes in medical personnel and sedation goals. Although no true reference measure or criterion exists for sedation assessment, several subjective patient assessment scoring systems have been developed. References to these can be found in the accompanying campaign document 'Critical Care References and Bibliography' available at www.patientsafetyfirst.nhs.uk.

However, these scales are not substitutes for the standard of interruption of sedation. In the Kress trial, patients were in fact subjected to both a sedation scale and interruption of sedation.

Should I include patients with tracheostomy in the ventilator bundle?

Yes.

Why is subglottic suctioning not included in the ventilator bundle?

Subglottic suctioning may be a very effective therapy for reducing the incidence of VAP. Recent studies have demonstrated efficacy of this approach. A meta-analysis assessed the effect of subglottic secretion drainage on the incidence of VAP and found that subglottic suctioning reduced the incidence of VAP by nearly half (risk ratio 0.51; 95% CI 0.37-0.71). Nevertheless, part of the aim of a bundle strategy is to implement solutions that are rapidly and readily available to hospitals. In addition, there is a tendency among providers to do all possible interventions, when a select few might be effective to minimise risks. Given the experience with the ventilator bundle that demonstrates near zero rates of VAP for prolonged periods of time with the 4 strategies that are included in the bundle when reliably applied, other strategies may not be necessary.

NB: Subglottic suctioning is included in the Savings Lives Ventilator Care bundle, as are a number of other elements. If you are already successfully implementing that bundle you should continue to do so.

We cannot agree on a definition of VAP. Is there a recommended definition we can use?

This is a common dispute in the early stages of this intervention and has been known to delay starting implementation for up to a year! Contact some hospitals who have already settled on a definition for some initial ideas. Pick one to start with so you can commence the work even if the discussions as to how best to refine it continue behind the scenes. Consistency is important so do not keep changing the definition; once the team has agreed the final definition, stick to it and be sure to annotate this change on your run chart.

Implementing the Central Line Bundle

This bundle has five key components:

1. Hand hygiene
2. Maximal barrier precautions
3. Use of 2% Chlorhexidine skin antisepsis
4. Optimal catheter site selection, with subclavian vein as the preferred site for non-tunnelled catheters in adults and avoidance of the femoral site
5. Daily review of central line necessity with prompt removal of unnecessary lines

In addition, good maintenance should include:

- Total Parenteral Nutrition (TPN) should be given via a separate line or a dedicated lumen
- Access to line must be made using a clean technique
- Entry site to be checked every day for signs of leakage or inflammation and line removed promptly if these signs are present.

What are we trying to achieve?

In order to agree your aim you need to understand the current state. Find out if you are already using any of the bundle elements as standard. If you already have the bundle in place, perform an audit to find out your current level of compliance. This helps you to set a realistic timeframe for your goal.

An example of an aim statement could be:

We will reduce the rate of central line infections by 50% in 1 year by achieving 95% compliance with the Central Line Bundle.

How will we know a change has been an improvement?

Measurement is the only way to know whether a change represents an improvement.

Create your operational definition. It is critical that teams determine some set of criteria by which they will define a central line infection in their organisation. Once this has been established, all stakeholders will share a common understanding of what exactly qualifies as a central line infection and what does not.

Likewise, the best-performing teams will develop their own standard criteria in order to know if a line is truly necessary or simply a convenience, and work to apply this routinely to all cases. Similar arrangements and customisations can be made for other aspects of the bundle, such as criteria for optimal site selection and what constitutes a 'clean technique'.

Decide what measures will inform you of your progress and how you are going to collect them. There are two measures for this intervention that are recommended for reporting to Patient Safety First via the on line extranet site:

- Central Line Bundle compliance
- Days between Central Line Infections.

Measure	How to calculate	Guidance
Central Line Bundle compliance	<ul style="list-style-type: none"> • Determine the numerator: the number of patients in the sample who had lines inserted using all 5 components of the bundle • Determine the denominator: the total number of central lines inserted • Calculate the percent compliance by dividing the numerator by the denominator and multiplying the result by 100 	<ul style="list-style-type: none"> • There should be no sampling for this measure. All patients with central lines inserted should be reviewed for compliance • Use daily goals sheet or consultant order sheet as the primary data source or direct observation • Remember this is a YES/NO outcome – only patients receiving all 5 components of the bundle are recorded as compliant • Remember to give credit where a reason for exclusion is documented • Perform the audit weekly but report to the extranet monthly. Aggregate the weekly results by totalling the numerator and denominator separately and entering them onto the extranet. The extranet will perform the relevant calculation.
Days between central line infections	<ul style="list-style-type: none"> • This measure is a cumulative count of the number of days that have gone by with no CLIs being reported. Every time an infection occurs the count is started over again. In this case, we are plotting successes between failures. The longer the run of cumulative successes (days with no CLI occurring) the better 	<ul style="list-style-type: none"> • Whenever events occur that are relatively rare in nature or when a ward or pilot area has sufficiently small numbers of events, the preferred way to go about analysing the data is to plot: (1) successes between failures, or (2) time between failures. Both of these techniques have been used in the Safer Patients Initiative work

Measure	How to calculate	Guidance
Central line infection rate	<ul style="list-style-type: none"> • Determine the numerator: The total number of CLI cases in the month • Determine the denominator: the total central line days in the month • Calculate CLI rate for 1000 catheter days by dividing the total number of CLIs occurring in the month by the total number of central line days in the month. Multiply the result by 1000 	<ul style="list-style-type: none"> • There should be no sampling for this measure • Report data monthly • Provide numerator and denominator when entering the data • The annotation section should be used to reflect any interventions that were made to reduce the infection rate

Some teams have preferred to use a sampling approach to assess compliance with the Central Line Bundle. For example, some teams use spot checks of compliance three times per week, others use daily checks of compliance at designated times. Regardless of the method, be sure to maintain the standard over time for accurate results.

- An example of an audit tool from the *Saving Lives* initiative can be found in *Appendix 2*
- An example of the audit tool used by the Manchester Critical Care Network can be found in *Appendix 4*.

Comparing CLI rates between hospitals

The practice of comparing rates of disease entities or patterns of therapy across institutions is commonly known as ‘benchmarking.’ Benchmarking, while commonly utilised to track performance, may not be a valid method to compare performance between facilities because of differences in patient population, resource availability, or severity of illness.

Currently, none of the work required to improve the care of central lines requires a comparison of rates between hospitals. As long as you establish methods in your organisation to determine the patterns and methods of your regular data collection, your results will be consistent over time with respect to your own performance and your own improvement, which is the primary interest.

Any benchmarking should be based on improvement, rather than comparing rates. If you learn of a hospital that has significantly improved, based on data and using the same measure over time, then learn from their work! Even if they are using a different definition from your hospital or treat some different populations, there will still be value in finding out what practices and changes they used to achieve their results.

What changes can we make that will result in an improvement?

The goal of the bundle is not to force a clinician to do anything that may be clinically inappropriate or cause harm in a unique situation. The elements apply to most patients, but there will always be exceptions. Deal with these in a way that makes sense. For example, if a patient is claustrophobic and panics about being under drapes, then modify the placement of drapes so that the patient is at ease and the site is protected; it is not beneficial to the patient to induce a panic attack. When exceptional situations arise, the key is for the team to discuss the elements, devise a sensible plan, and document it accordingly. Give credit for meeting the bundle element in such cases:

- **State the line day during rounds** to remind all as to how long the line has been in, e.g. 'Today is line day 6'
- **Post updates to results regularly and prominently.** Enthusiasm for the project will wane over time if clinical staff perceive that the leadership's enthusiasm has diminished. It is essential to regularly update all involved staff in the work on the monthly level of compliance and the monthly change in central line infection rates. Not only will this show dedication to the project but when the momentum becomes apparent, clinical staff will be aware of the progress
- **Discourage the tendency to select and try out items that seem easy at the expense of more difficult options also included in the bundle.** Your aim is 100% compliance with every bundle element for every patient; partial compliance is the equivalent of non-compliance. Remember though, to give credit for compliance if a bundle element is not given for clinically appropriate reasons, provided that the discussion with the team occurred and it is clearly documented.

1. Hand hygiene

All NHS organisations should be aware of the national initiatives to improve compliance with hand hygiene and many have implemented measures such as those listed below:

- Proper hand hygiene is required before and after palpating catheter insertion sites, inserting, replacing, accessing, repairing, or dressing an intravascular catheter. In addition, the use of gloves does not negate the need for hand hygiene
- Keep soap/alcohol-based hand hygiene 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
- Create an environment where reminding each other about hand hygiene is encouraged
- Initiate a campaign using posters including photos of celebrated hospital doctors/employees recommending hand hygiene.

The NPSA issued a new cleanyourhands alert (2nd September 2008). This alert provides guidance on best practice in hand hygiene at the point of care, to contribute to reducing healthcare associated infection (HCAI) in the NHS. It is based on the first hand hygiene alert issued four years ago with updated information on the point of care message, risk management and product procurement. Go to: www.npsa.nhs.uk/nrls/alerts-and-directives/alerts/clean-hands-save-lives.

2. Maximal barrier precautions

- Maximal sterile barrier precautions (e.g., cap, mask, sterile gown, sterile gloves, and large sterile drape) during the insertion of CVCs substantially reduces the incidence of central line associated bacteraemia compared with standard precautions (e.g., sterile gloves and small drapes)
- Keep equipment stocked in a trolley for central line placement to avoid the difficulty of finding necessary equipment to institute maximal barrier precautions
- If a full-size drape is not available, apply two drapes to cover the patient. Or consult with the operating room staff to determine how to procure full-size sterile drapes, since these are routinely used in surgical settings.

3. Use of 2% Chlorhexidine (alcoholic 70%) skin antiseptis

- Disinfect clean skin with an appropriate antiseptic before catheter insertion and during dressing changes
- Include chlorhexidine antiseptis kits in trolleys or grab bags storing central line equipment. If a prepacked central line kit includes povidone-iodine, the solution's use must be avoided. If there is good reason not to use chlorhexidine, such as a patient allergy, you should not feel forced into using it or fear being hurt on bundle compliance statistics if it is not used. If there is a good reason for an exception and it is documented, the intent has been met and teams should feel comfortable assigning compliance for that item
- Ensure that chlorhexidine solution dries completely before inserting the central line.

4. Optimal catheter site selection, with subclavian vein as the preferred site for non-tunnelled catheters in adults and avoidance of the femoral site

- The site at which a catheter is placed influences the subsequent risk for catheter-related infection and phlebitis. For adults, lower extremity insertion sites are associated with a higher infection risk than upper extremity sites. Subclavian site is preferred for this reason although other factors (e.g. catheter-operator skill) should be considered when deciding where to place the catheter
- Include the order of preference for site in the line placement checklist with an appropriate area for documenting reasons for not using the first choice.

5. Daily review of central line necessity with prompt removal of unnecessary lines

- One of the most effective strategies for preventing central line associated infections is to eliminate, or at least reduce, exposure to central venous catheters. The decision regarding the need for a catheter however is complex and therefore difficult to standardise into a practice guideline. Nonetheless, a local strategy to systematically evaluate daily whether any can be removed should be developed
- A contemporaneous record documenting line placement and site care can help with prompting early removal. The decision as to whether the form becomes a permanent part of the medical record, or is simply used as a data collection tool, must be made locally at each hospital. These strategies are particularly effective if used in conjunction with a Daily Goals assessment sheet. This form can be completed during daily rounds on the patient.

Using the PDSA cycle

- Work with one doctor to identify a patient who will receive the bundle
- Work with the doctor inserting the line and assisting staff to be sure they are able to follow the bundle and implement the checklist
- Process feedback and incorporate suggestions for improvement
- Engage in additional PDSA cycles to refine the process and make it more reliable.

Once you have a stand alone process that works:

- Make sure that the approach can be carried over from shift to shift to eliminate gaps in teaching and utilisation
- Once the intervention has been applied in one area or unit begin the PDSA cycle again in a new location.

Case study: Greater Manchester Critical Care Network/NHS North West Collaborative Procurement Hub

Representatives from critical care clinical teams across the Greater Manchester Network have been working in partnership with the NHS North West Collaborative Procurement Hub to address some of the practical issues and barriers experienced in relation to infection risks associated with central venous catheter insertion. Successful completion of two workstreams has resulted in improved management of patients requiring CVCs.

The first project looked at the reasons behind why antimicrobial impregnated CVCs were not being used when clinically indicated. The key prohibitive issue was the cost of the catheters. Following consensus agreement by the clinical stakeholders on the choice of a standard catheter, the CPH were able to negotiate a very competitive price for antimicrobial impregnated catheters for member Trusts. As a result of this project, antimicrobial impregnated catheters are more readily available to patients who fulfil the care bundle criteria.

This work led to a second project whereby a standard sterile CVC insertion pack was agreed. This project also followed a competitive tendering process which resulted in the packs being cost neutral or cost saving. The success of this project has resulted in non critical care areas also adopting the use of the pack across a number of organisations. Although there is no evidence to demonstrate a reduction in risk, there is certainly a sense that standardising practice by providing all the necessary equipment to insert a catheter will have positive clinical effects.

General Questions Relating to the Central Line Bundle

What is a central line?

Neither the type of line alone nor the site of insertion can determine if a line is a central line. Generally speaking, if the line terminates in a great vessel, it is a central line. The exact definition should be determined locally.

Why are subclavian lines preferred over PICC lines if the standard is lowest infection risk?

Data is still lacking on infection rates for PICC lines in acute care settings as opposed to chronic or home care settings. The most recent evidence suggests that infection rates rival those of subclavian or internal jugular catheters placed in the acute care setting. No head-to-head comparison has yet been done to make a definitive conclusion. In addition, PICCs are more vulnerable to thrombosis and dislodgment, and are less useful for drawing blood specimens. Moreover, PICCs are not advisable in patients with renal failure and impending need for dialysis, in whom preservation of upper-extremity veins is needed for fistula or graft implantation given a possibly greater risk of subclavian vein stenosis.

Does everyone in the room need to gown and glove when a central line is placed, or just the nurse assisting the procedure directly and dropping items onto the sterile field?

The best advice is that the placement of a central line should be considered analogous to a surgical procedure. This means anyone in direct contact with the field should wear a sterile gown and gloves, a mask, and a hat that covers all hair. This is in accordance with the guidelines produced by the Association of Anaesthetists. The minimum for any person dropping items onto the field should be a plastic apron, gloves, and hat.

'Infection Control in Anaesthesia'; The Association of Anaesthetists of Great Britain and Ireland. November 2002.

Why is a full-size drape essential for maximal barrier precautions?

Studies that demonstrate the effectiveness of maximal barrier precautions have employed a full-size drape. These studies show dramatic reductions in risk when maximal barrier precautions are used. It is not possible to clearly separate out the effect of a full-size drape from these trials versus the other components of maximal barrier precautions such as gowns, gloves, eyewear, etc. In the absence of such information and given striking results of interventions that include a full-size drape, not using the larger drape could only add an unnecessary element of risk to an otherwise simple procedure. Using the analogy to surgery as cited immediately above, it would be unimaginable for a patient to undergo any surgical procedure in the operating room without a full-size drape in place.

I read that the central line bundle as written is designed to apply only to patients in the ICU. I want to include patients in Accident & Emergency and post operative recovery area. Why do you advise to use the bundle in ICU?

The reason for recommending application of the central line bundle in the ICU has more to do with improvement methods and less to do with the utility of the intervention. It was originally tested with ICU teams working to improve teamwork and communication for improved outcomes. It is hoped that by starting in the ICU hospitals will become expert in application of the bundle in one location, develop the skill and manpower to spread the practice to other areas of the hospital, and ultimately do so.

In general, we recommend starting small and spreading changes to larger domains over time. There is no reason not to apply the central line bundle in all areas that central lines are placed and where you can gain the cooperation of staff. However, it may be wiser to perfect the practice in one location than to launch an overly broad initiative that might fail before it begins.

Be sure to check for guidelines from clinical expert panels related to other locations before spreading.

What are the inclusion and exclusion criteria for application of the central line bundle (for the individual bundle elements)?

No specific exclusion criteria exist, but good clinical judgment should be exercised in conjunction with a close reading of the evidence base. Likewise, no specific inclusion criteria are available. Instead, teams interested in improving their performance should develop these standards in conjunction with their clinical staff and apply them uniformly over time. In so doing, teams will have an accurate standard whereby they can measure their own progress in comparison to the only standard that is truly meaningful: their own data.

As an example, some institutions have decided that the central line bundle cannot be applied in settings such as Accident & Emergency Department. Accordingly, they have created policies and procedures to re-site those lines if a patient is subsequently admitted to a critical care unit. Policies such as this are best left to the discretion of the individual organisations.

Workable inclusion criteria, exclusion criteria, measurement systems, and protocols all require customisation at the local level to be effective. The only key factor in all of these decisions is that the standards, once decided, are adhered to over time.

Appendix 1

Example of a Ventilator Care Bundle audit chart

VENTILATED CARE BUNDLE AUDIT FORM - UNIT _____

NETWORK _____
 TRUST _____
 HOSPITAL _____
 LEAD CONTACT _____
 DATE _____

Recs.	DVT/Thrombosis		GU/Infections		Head Elevation (30 degrees)		Suctioning	
	Yes	No	Local Exclusion	Yes	No	Local Exclusion	Yes	No
1								
2								
3								
4								
5								
6								
7								
8								
9								
10								
TOT								
N								

Appendix 2

Example of care bundle audit tool

Saving Lives: delivering clean and safe care. Department of Health.

High Impact Intervention No.1: Central venous catheter insertion

Available at www.clean-safe-care.nhs.uk

Care elements Observation	Care element 1	Care element 2	Care element 3	Care element 4	All elements performed
1	✓		✓	✓	
2	✓	✓		✓	
3	✓	✓	✓	✓	✓
4	✓	✓	✓		
5	✓	✓	✓	✓	✓
Total number of times an individual element was performed	5	4	4	4	2
% when element of care was given	100%	80%	80%	80%	40%

This example shows that while most care elements were performed on only two occasions were ALL elements performed correctly. Overall compliance with all elements was only 40% and as a result the risk of infection was significantly increased.

Appendix 3

PDSA Form – Example of a form to document a first PDSA cycle in implementing a ventilator bundle. Institute for Health Improvement



Project: Ventilator -Associated Pneumonia - Daily Goals Assessment

PDSA Cycle: Test the use of a daily goal assessment form to achieve compliance with the ventilator bundle.

PLAN:

Questions: Will the use of the Daily Goals Assessment form ensure total ventilator bundle compliance?

Predictions: Using the Daily Goals Assessment form during daily rounds will help ensure total compliance with all elements of the ventilator bundle appropriate for patient .

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

What: Use the Daily Goals Assessment form at daily rounds for one day.

Who: Mike (physician in charge of rounds) and others who attend rounds .

Where: Patient rooms

When: Tomorrow

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

Who: Mike (physician in charge of rounds) leaves form on patient chart , nurse on improvement team reviews form for compliance with all ventilator bundle components.

What: Record compliance with all ventilator bundle elements.

When: During daily rounds

Where: Daily Goals assessment form on patient chart

DO:

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

On Monday, the form was used during daily rounds. A form was completed and placed on each chart during the rounding process.

STUDY:

Complete analysis of data: 50% of the patients had all elements of the bundle in place at the time of rounds.

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

The form made it easier to document bundle compliance , but its use did not improve it on first day.

Summarize the new knowledge we gained by this cycle:

We need to do some additional tests to improve compliance with the bundle so that on next rounds the numbers are improved.

ACT:

List actions we will take as a result of this cycle: Team will meet to develop additional tests.

Plan for the next cycle (adapt change, another test, implementation cycle?): We will use the form again tomorrow to track our data.

Appendix 4

Example audit tool used by the Manchester Critical Care Network

AUDIT and CHECKLIST for CVC INSERTION
Please read before procedure and complete afterwards

First Central Venous Catheter insertion?		Y/N	
If No please indicate number of previous lines		
A. Choice of line		Tick box	
Single lumen - antibiotic impregnated <i>Preferred unless multiple ports are essential for patient care</i>		-	
Multiple lumen - antibiotic impregnated * <i>Haemodynamic monitoring + drugs + fluid + hyperalimentation</i>		-	
P.I.C.C. <i>4-6 weeks IV access</i>		-	
Tunnelled Hickman <i>4+ weeks IV access</i>		-	
Portacath		-	
B. Choice of site			
Subclavian <i>Lowest risk of infection</i>		-	
Internal Jugular <i>Less risk of mechanical complications</i>		-	
Femoral <i>AVOID, replace as soon as patient stable</i>		-	
C. Use of Personal Protective Equipment and Infection Control Procedures			
Hand washing		-	
Maximal sterile barrier precautions:		-	
Gloves (essential)		-	
Gown (essential)		-	
Drapes (essential)		-	
Face/Eye protection (risk assess)		-	
Cutaneous asepsis			
Before insertion	2% chlorhexadine with 70% isopropyl alcohol	**	Y/N
	Allowed to dry before insertion of CVC	Y/N	
After insertion	2% chlorhexadine with 70% isopropyl alcohol	**	Y/N
	Allowed to dry		Y/N
Dressing	Semi-permeable transparent dressing	Y/N	
	Sterile gauze dressing	Y/N	
Appropriate disposal of sharps			Y/N
D. Other actions			
Documented in patient notes?		Y/N	
Start visual infusion phlebitis (V.I.P) chart?		Y/N	
Designate port for hyperalimentation	<i>(Multiple lumen only)</i>		Y/N/NA

Date Patient's Hospital / NHS no
Setting (ward / theatre) Division

*use for short term insertions i.e. <3wks and when aseptic technique at insertion is compromised, patients with extensive burns, patients with prosthesis in situ and ITU patients
** use povidone iodine solution as an alternative in allergy