

**Action deadlines for the Safety Alert
Broadcast System (SABS)**

Category: ACTION

For action by: clinical leads for critical care units
in acute and foundation trusts

**Deadline (action 1.1 underway):
26 September 2008**

**Deadline (action 1.1 complete):
27 November 2008**

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Technical patient safety solutions for ventilator-associated pneumonia in adults

1 Action

- 1.1 Mechanically ventilated patients who are intubated should be positioned with their upper body elevated (in a semi-recumbent or seated position) for as much of the time as possible. For some patients this will not be appropriate (for example, those with spinal injuries).
- 1.2 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.

2 Other interventions evaluated

- 2.1 This guidance is not intended as a comprehensive overview of interventions aimed at preventing ventilator-associated pneumonia (VAP); (see section 4 for information on current practice, including guidelines from other organisations). The interventions in section 1 are those for which the evidence was considered adequate to recommend them as actions to the NHS in England and Wales. The Patient Safety Advisory Committee also examined evidence on other interventions, which may have benefits in the prevention of VAP, and reached the following conclusions.
- 2.2 The Committee examined evidence which suggested that selective decontamination of the digestive tract (SDD) using topical antibiotics may

reduce the incidence of VAP and that SDD regimes that include systemic antibiotics may also reduce mortality. However, Specialist Advisers stated that UK intensive care specialists had particular concerns about the risk of infection with *Clostridium difficile* and the induction and/or selection of resistant, including multiresistant, microorganisms as a result of SDD. Therefore the Committee recommended further research into SDD in a UK setting (see section 7.2).

- 2.3 A lack of robust evidence meant the Committee was unable to make recommendations for action on the use of kinetic beds.
- 2.4 Although the evidence supported the use of elements of care bundles, there was insufficient evidence to recommend a care bundle of any specific design.
- 2.5 Further information is given in section 5.

3 The patient safety problem or harm

- 3.1 Pneumonia is an inflammatory condition of the lungs caused by bacterial, viral or fungal infection. VAP can occur as a complication of mechanical ventilation, particularly when ventilation is required for a prolonged period of time and in patients who are critically ill. VAP can be caused by a range of microorganisms, some of which are resistant to many antimicrobials. These microorganisms are normally found in the throat (specifically, the

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NICE patient safety guidance advises on how to improve the safety of patients in the NHS in England and Wales.

oropharynx) and the gut. Mechanical ventilation allows the microorganisms to move to the lungs, despite the best standards of ventilator use.

3.2 There is no generally accepted definition of VAP in mechanically ventilated patients, but it is often defined as pneumonia that develops 48 hours or more after intubation with an endotracheal or tracheostomy tube, and that was not present before intubation. Definite diagnosis may not be straightforward because there are no firm diagnostic criteria for VAP; it is generally diagnosed on the basis of clinical signs and symptoms and chest X-rays and is confirmed microbiologically.

3.3 VAP is recognised as a significant problem in the USA, where data suggest that it represents 31% of all intensive care unit (ICU)-acquired infections, and that it occurs in 9–27% of all intubated patients. There are no data on the incidence of VAP in the UK. The lack of an accepted definition and firm diagnostic criteria contribute to the difficulty in collecting this information.

3.4 Patients who develop VAP are at risk of serious complications (for example, acute respiratory distress syndrome) and have a significantly longer duration of mechanical ventilation and ICU stay. Data from the USA indicate that the mortality rate of patients who have developed VAP is between 38% and 50%. However, many patients with VAP have other serious comorbidities which make it difficult to establish any direct causal link between VAP and mortality. It should be noted that the comorbidity profiles of patients receiving mechanical ventilation in the USA and UK may be different.

4 Current practice

4.1 Anecdotal evidence suggests that in the UK there is substantial variation in VAP prevention strategies.

4.2 The Health Act 2006 Code of Practice requires NHS organisations to audit policies and procedures to prevent infection. To support this requirement, the Department of Health (DH) published a high impact intervention for ventilated patients in June 2007. This uses a care bundle approach with an accompanying tool to enable organisations to demonstrate compliance with the Code of Practice. The interventions specified in the high impact intervention are as follows, and include the two recommended technical patient safety solutions:

- elevation of the head of the bed to 30–45 degrees
- sedation holding/review
- deep vein thrombosis prophylaxis
- gastric ulcer prophylaxis
- appropriate humidification of inspired gas
- appropriate ventilator tubing management
- suctioning of respiratory secretions (including use of gloves and decontaminating hands before and after the procedure)
- routine oral hygiene as per local policy.

4.3 The British Society for Antimicrobial Chemotherapy has developed guidelines on the diagnosis, prevention and treatment of VAP¹.

5 Basis for guidance

5.1 Summary

5.1.1 Children under the age of 16 years were outside the scope of this guidance.

5.1.2 The published scientific evidence evaluated on all of the potential patient safety solutions was relatively poor. However, the actions in section 1 were considered by the Committee to have low potential for harm and were supported by credible efficacy data and expert advice. The actions were considered to be relatively easy to implement and associated with little or no additional resource.

5.2 Body position

5.2.1 Two randomised controlled trials (RCTs) compared the incidence of VAP in mechanically ventilated patients positioned in either a semi-recumbent position (45 degrees) or a supine position. One well-conducted RCT of 86 patients found that the semi-recumbent position significantly reduced the frequency of clinically suspected and microbiologically confirmed pneumonia. The incidence of VAP was 3/39 (8%) in the semi-recumbent group compared with 16/47 (34%) in the supine group (relative risk [RR] 0.23, 95% confidence interval [CI] 0.07 to 0.72). A second RCT reported that the incidence of VAP was 12/112 (11%) in the semi-recumbent group compared with 8/109 (7%) in the supine position (RR 1.46; 95% CI 0.62 to 3.43). However, the intended angle of 45 degrees was only achieved in the semi-recumbent patients for 15% of the time; the average angle attained was 28 degrees. A third RCT found that the incidence of VAP in the prone position was 5/25 (20%) compared with 10/26 (38%) in the supine position (RR 0.52; 95% CI 0.21 to 1.31).

5.2.2 The cost effectiveness of placing the patient in a semi-recumbent position was not evaluated as it was not associated with any readily identifiable costs. It is one element of the advanced nursing care required by ventilated patients.

5.2.3 It was noted that placing the patient in a semi-recumbent position was a component of all the care bundles identified.

5.2.4 All the Specialist Advisers considered that placing the patient in a semi-recumbent position was efficacious in reducing the risk of VAP. They thought that it should be routine practice and saw few obstacles to implementation. However, it was clear that it would not be appropriate to place some patients in a semi-recumbent position (for example, those with spinal injuries).

¹ Masterton RG, Galloway A, French G et al. (2008) Guidelines for the management of hospital-acquired pneumonia in the UK: Report of the Working Party on Hospital-Acquired Pneumonia of the British Society for Antimicrobial Chemotherapy. *The Journal of Antimicrobial Chemotherapy* 62: 5–34.

5.2.5 Concerns were raised in the Assessment Report about body elevation causing skin shearing and pressure sores, but the Committee was advised that patients would routinely be receiving appropriate preventative care.

5.3 Prophylactic antimicrobials

Antiseptics

5.3.1 The published systematic reviews considered by the Committee included a total of nine RCTs. The RCTs investigated oral decontamination of mechanically ventilated patients using a range of chlorhexidine antiseptic regimens (0.12–2%). One RCT investigated the use of povidone iodine (10%). The systematic review authors concluded that oral decontamination using antiseptics is associated with a lower risk of VAP but noted that the meta-analysis did not show any significant reduction in mortality, duration of mechanical ventilation or duration of ICU stay.

5.3.2 The Committee sought evidence on complications associated with chlorhexidine. It noted that anaphylaxis and serious respiratory complications associated with chlorhexidine are extremely rare.

Antibiotics

5.3.3 One published systematic review included four RCTs which examined topical application of antibiotics to the mouth. The authors concluded that oral decontamination using topical application of antibiotics did not significantly reduce the incidence of VAP, mortality, duration of mechanical ventilation or duration of ICU stay.

5.3.4 The Committee considered nine systematic reviews on SDD. The academic group undertook a new systematic review that included a meta-analysis of data from 27 RCTs. Data from this meta-analysis suggested that SDD using non-absorbable antimicrobials applied to the oropharynx and through a nasogastric tube may reduce the incidence of VAP. In addition, the new meta-analysis indicated that SDD regimes that include systemic antibiotics may also reduce mortality. These findings were consistent with those in the nine published systematic reviews. There was limited reporting of safety data; none of the RCTs indicated that serious adverse effects were associated with SDD. There were some reports that oropharyngeal paste formulations were not acceptable to some patients and that the enteral antibiotics could cause gastrointestinal problems.

5.3.5 The results of the economic evaluation indicated that SDD is very likely to be a cost-effective intervention if it is assumed that SDD reduces the incidence of VAP, and that VAP increases mortality and length of stay (either ICU or hospital), and reduces quality of life. However, the Committee was concerned about the reliability of the final estimates because the economic evaluation was primarily based on RCTs that had been undertaken over 10 years ago in non-UK populations. The RCTs also did not take account of the potential

impact of *Clostridium difficile* and resistant and multiresistant microorganisms.

5.3.6 The Specialist Advisers stated that there was concern about *Clostridium difficile* and the risk of increasing antibiotic resistance through the use of antibiotics in SDD. They pointed out that few of the studies had been undertaken in the UK, and therefore they did not reflect current NHS practice or, potentially, the range of infecting microorganisms encountered in the UK. In particular, many of the trials were carried out in countries with low incidences of methicillin-resistant *Staphylococcus aureus* (MRSA).

5.4 Use of kinetic bed therapy

5.4.1 The review group identified two meta-analyses on kinetic bed therapy (which is known by a number of names including oscillatory therapy). Only one of the meta-analyses was judged to be methodologically robust, however, the authors reported that the methodological quality of all 15 of the RCTs included in the meta-analysis was poor and none met all of their validity criteria. The authors pooled the data available from 10 of the RCTs. The pooled data indicated that kinetic bed therapy reduced the incidence of VAP compared with manual turning (odds ratio [OR] 0.38; 95% CI 0.28 to 0.53, $p < 0.001$) but did not reduce mortality, duration of mechanical ventilation, or duration of ICU or hospital stay. Kinetic beds were poorly tolerated by conscious patients, resulting in a high withdrawal rate from the studies. Only one RCT undertook an intention-to-treat analysis. The authors of the meta-analysis expressed concern that the lack of allocation concealment and blinding could introduce bias into the diagnosis of pneumonia. The authors also expressed concern that the potential complications of kinetic bed therapy, including those arising from increased sedation, had not been systematically addressed. One of the RCTs identified a number of serious complications, including disconnection of intravascular catheters. In addition, there was no information available to determine the effectiveness of the different rotation parameters of the kinetic beds.

5.4.2 The results of the cost-effectiveness evaluation, based on data from the RCTs, indicated that, although there is uncertainty around the mean incremental cost-effectiveness ratio (ICER), kinetic bed therapy would be associated with lower overall costs (costs associated with bed hire and costs arising from acquiring VAP) than not undertaking any intervention to prevent VAP.

5.4.3 In considering the use of kinetic beds, the Committee noted that the trials were of poor methodological quality and that potentially serious complications had not been systematically evaluated. It also noted that many conscious patients find kinetic beds unacceptable. The Committee considered that there may be some subgroups of ventilated patients for whom kinetic beds are appropriate, but no good evidence was identified.

5.4.4 The Committee also took account of the views of the Specialist Advisers who stated that kinetic beds may interfere with other aspects of nursing care. The Advisers noted that there is limited experience with kinetic beds in the UK and that they are used infrequently. They also pointed out that there are concerns about decontamination of kinetic beds.

5.5 Care bundles

5.5.1 A number of different care bundles have been produced for patients receiving mechanical ventilation. They include some measures relating directly to the prevention of VAP and others relating to the overall management of ventilated patients. There have been no RCT evaluations of care bundles. Two before-and-after studies conducted in the USA reported reduced incidences of VAP following the introduction of two different care bundles, from 22–33 cases per 1000 bed days to 0–13 cases per 1000 bed days in one study, and a reduction from 8 cases per 1000 bed days to 3 cases per 1000 bed days in the second study. The components of the care bundles differed between the studies, and it was not possible to determine the benefit of individual components. The authors of the second study, however, believed that elevating the head of the bed and oral care had a major impact in reducing the incidence of VAP.

5.5.2 The results of the economic evaluation indicated that the care bundle with the most components (the first of those described in section 5.5.1) was likely to be cost effective.

5.5.3 All the Specialist Advisers considered care bundles to be a good approach to the management of ventilated patients and likely to improve outcomes and reduce the incidence of VAP. However, it was noted that there was insufficient evidence for the recommendation of any particular care bundle. The Specialist Advisers stated that there is a lack of awareness and understanding among ICU staff about the care bundle approach and there would be a need for training to support implementation. There was support for a number of the individual components of care bundles, and the Specialist Advisers thought that these should be part of routine clinical practice. It was noted that the DH had recently published a UK care bundle (see section 4.2).

For further information please see the systematic review for the prevention of ventilator-assisted pneumonia (www.nice.org.uk/patientsafety/index.jsp?action=pilot&o=11770).

6 Implementation

The Healthcare Commission assesses the performance of NHS organisations in meeting core standards set by the Department of Health in 'Standards for better health' issued in July 2004. Core standard C1(b) states that healthcare organisations should ensure that patient safety notices, alerts and other communications concerning patient safety which require action are acted upon when required.

'Healthcare standards for Wales' was issued by the Welsh Assembly Government in May 2005 and provides a framework both for self-assessment by healthcare organisations and for external review and investigation by Healthcare Inspectorate Wales. Standard 12b requires healthcare organisations to ensure that patients and service users are provided with effective treatment and care that conforms to NICE guidance.

6.1 Assessing the impact of the guidance

The impact of the action alert will be tracked in England through the safety alert broadcast system (SABS; www.info.doh.gov.uk/sar/cmopatie.nsf) and in Wales through the regional offices of the Welsh Assembly Government. In addition, healthcare organisations are expected to use indicators, audit tools and patient safety incident reports to monitor the continued implementation of the patient safety recommendations. Clinical governance groups in organisations should review these data annually and take appropriate action to ensure patient safety. Healthcare commissioners and performance management groups should also review these data and any resulting actions taken by the organisation annually. The NPSA will also review these data to gain feedback on the impact of the patient safety guidance.

6.2 Implementation tools

NICE has developed tools to help organisations implement this guidance (listed below). These are available on our website: www.nice.org.uk/PSG002

- Slides highlighting key messages for local discussion.
- A costing statement explaining the resource impact of this guidance.
- Audit support for monitoring local practice.

7 Research recommendations

7.1 A national data collection initiative is required to provide epidemiological data on the incidence of VAP in the UK. This could involve the Intensive Care National Audit and Research Centre (ICNARC) and/or the Health Protection Agency. This initiative should include agreement of a case definition to overcome the variation in diagnostic criteria.

7.2 Research into SDD as a means of preventing VAP is required in a UK setting. This should investigate microbiological outcomes including infection with *Clostridium difficile* and resistant microorganisms in the context of well-defined policies of antibiotic use. Studies should define clearly what other prophylactic methods (such as elevation of the upper body) are used. Information about barriers to implementation of SDD regimes would also be helpful.

7.3 Further research into different antiseptics for oral decontamination is required, including type of antiseptic, the optimal concentration and frequency of application in different groups of patients.

8 Further information

8.1 Ordering information

You can download the following documents from www.nice.org.uk/PSG002

- Patient safety guidance – this document.
- 'Understanding NICE guidance' – information for patients and carers.
- Details of all the evidence that was looked at and other background information.

For printed copies of the patient safety guidance or 'Understanding NICE guidance', phone NICE publications on 0845 003 7783 or email publications@nice.org.uk and quote:

- N1656 (patient safety guidance)
- N1657 ('Understanding NICE guidance').

8.2 Related NICE/NPSA guidance

- Acutely ill patients in hospital: recognition of and response to acute illness in adults in hospital. NICE clinical guideline 50 (2007). Available from: www.nice.org.uk/CG050
- Clean hands help to save lives. NPSA patient safety alert 04 (2004). Available from: www.npsa.nhs.uk/patientsafety/alerts-and-directives/alerts/clean-hands
- Infection control: prevention of healthcare-associated infection in primary and community care. NICE clinical guideline 2 (2003). Available from: www.nice.org.uk/CG002

9 Review of guidance

9.1 The decision to review this patient safety guidance will be taken in consultation with stakeholders and in the light of information gathered by NICE and the NPSA, and research findings.

9.2 This patient safety guidance will be considered for review by the NPSA in August 2011.

Andrew Dillon NICE

Chief Executive

August 2008

Sources of evidence

The following documents, which contain the evidence, were considered by the Patient Safety Advisory Committee when making its recommendations. They are available from www.nice.org.uk/PSG002

- Systematic review of selective decontamination of the digestive tract for the prevention of ventilator-associated pneumonia (2008).
- Economic model of selective decontamination of the digestive tract for the prevention of ventilator-associated pneumonia (2008).
- Specialist adviser comments on selective decontamination of the digestive tract for the prevention of ventilator-associated pneumonia (2008).
- Systematic review for the prevention of ventilator-associated pneumonia (2007).
- Economic model for the prevention of ventilator-associated pneumonia (2007).
- Specialist adviser comments on the prevention of ventilator-associated pneumonia (2007).
- Patient group feedback on the prevention of ventilator-associated pneumonia (2007).

This guidance represents the view of the Institute and the NPSA, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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