NATIONAL QUALITY FORUM

Measure Submission and Evaluation Worksheet 5.0

This form contains the information submitted by measure developers/stewards, organized according to NQF's measure evaluation criteria and process. The evaluation criteria, evaluation guidance documents, and a blank online submission form are available on the submitting standards web page.

NQF #: 1861　　　NQF Project: Pulmonary Project
(for Endorsement Maintenance Review) Original Endorsement Date:　Most Recent Endorsement Date:
BRIEF MEASURE INFORMATION
De.1 Measure Title: National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure
Co.1.1 Measure Steward: Centers for Disease Control and Prevention
De.2 Brief Description of Measure: The measures are two Standardized Incidence Ratios (SIR) for healthcare-associated, ventilator-associated events (VAEs) among adult patients, >=18 years old, in acute and long-term acute care hospitals and inpatient rehabilitation facilities, receiving conventional mechanical ventilator support for >=3 calendar days. Persons receiving rescue mechanical ventilation therapies are excluded. The two SIRS are for: 1.　　Ventilator-Associated Conditions (VAC) 2.　　Infection-related Ventilator-Associated Complications (IVAC) These "Standardized Incidence Ratios" are analogous to the "Standardized Infection Ratios" for selected healthcare-associated infections that have previously been submitted to NQF by the Centers for Disease Control and Prevention (CDC). Because the VAE algorithm will capture events that are not infection-related, as well as some that are infection-related, "SIR" in the context of this submission refers to "Standardized Incidence Ratio." The SIRs for VAC and IVAC are proposed to replace the previously-endorsed NQF measure for Ventilator-Associated Pneumonia (VAP) that had been maintained by CDC: Ventilator-associated pneumonia for ICU and high-risk nursery [HRN] patients (NQF measure #0140). CDC no longer supports that measure and plans to discontinue its use in the National Healthcare Safety Network (NHSN). The transition from reporting infection or event rates to reporting SIRs is consistent with CDC's decision to use the Standardized Infection Ratio (SIR) as the summary measure for healthcare-associated infections (HAIs), including catheter-associated urinary tract infections (CAUTIs), central line-associated bloodstream infections (CLABSIs), and surgical site infections (SSIs). CDC previously submitted SIR-based measure proposals to NQF for CAUTIs, CLABSIs, and SSIs. The SIR enables summarization of healthcare-associated event data across multiple strata, e.g., different ICU types, into a single statistic, adjusting for differences in event incidence among those strata and obviating the need to report separate event rates for each stratum. The SIR compares the observed to expected infection experience (or event experience, in the case of VAEs) for each stratum. The number of expected infections or other healthcare-associated events is derived from the infection or event experience for a specific stratum in a standard population during a baseline time period. For example, the expected value for a HAI among medical intensive care unit (MICU) patients may be derived from the infection experience among all MICU patients reported to NHSN for the years 2006-2008. The VAE algorithm included in this measure proposal was developed in collaboration with the CDC Prevention Epicenters and with the Ventilator-Associated Pneumonia Surveillance Definition Working Group. The Working Group is composed of representatives of several key societies and organizations. Member organizations and individual representatives are listed in Co.6. and Ad.1. of this submission.
2a1.1 Numerator Statement: VAC: Total number of observed healthcare-associated VACs among adult patients in acute and long-term acute care hospitals and inpatient rehabilitation facilities

IVAC: Total number of observed healthcare-associated IVACs among adult patients in acute and long-term acute care hospitals and inpatient rehabilitation facilities

2a1.4 Denominator Statement: VAC: Total number of expected VACs, calculated by multiplying the number of ventilator days for each location under surveillance for VAEs during the period by the VAC rate for the same types of locations obtained from the standard population.

IVAC: Total number of expected IVACs, calculated by multiplying the number of ventilator days for each location under surveillance for VAEs during the period by the IVAC rate for the same types of locations obtained from the standard population.

2a1.8 Denominator Exclusions: Patients receiving non-conventional (rescue) mechanical ventilation therapies are excluded. Rescue mechanical ventilation therapies that are excluded from VAC and IVAC surveillance include (but are not limited to) the following: high-frequency mechanical ventilation, mechanical ventilation in the prone position, and extracorporeal membrane oxygenation.

1.1 Measure Type: Outcome
2a1. 25-26 Data Source: Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Paper Records
2a1.33 Level of Analysis: Facility, Population : National, Population : State

1.2-1.4 Is this measure paired with another measure? No

De.3 If included in a composite, please identify the composite measure (*title and NQF number if endorsed*):

STAFF NOTES (*issues or questions regarding any criteria*)

Comments on Conditions for Consideration:

Is the measure untested?   Yes☐ No☐   If untested, explain how it meets criteria for consideration for time-limited endorsement:

1a. Specific national health goal/priority identified by DHHS or NPP addressed by the measure (*check De.5*):
5. Similar/related endorsed or submitted measures (*check 5.1*):
Other Criteria:

Staff Reviewer Name(s):

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1. IMPACT, OPPORTUNITY, EVIDENCE - IMPORTANCE TO MEASURE AND REPORT

Importance to Measure and Report is a threshold criterion that must be met in order to recommend a measure for endorsement. All three subcriteria must be met to pass this criterion. See guidance on evidence.
Measures must be judged to be important to measure and report in order to be evaluated against the remaining criteria. (evaluation criteria)

1a. High Impact: H☐ M☐ L☐ I☐
(*The measure directly addresses a specific national health goal/priority identified by DHHS or NPP, or some other high impact aspect of healthcare.*)

De.4 Subject/Topic Areas (*Check all the areas that apply*): Infectious Diseases : Respiratory, Pulmonary/Critical Care, Pulmonary/Critical Care : Critical Care, Pulmonary/Critical Care : Pneumonia
De.5 Cross Cutting Areas (*Check all the areas that apply*): Population Health, Safety : Complications, Safety : Healthcare Associated Infections

1a.1 Demonstrated High Impact Aspect of Healthcare: Affects large numbers, A leading cause of morbidity/mortality, Frequently performed procedure, High resource use, Severity of illness

1a.2 If "Other," please describe:

1a.3 **Summary of Evidence of High Impact** *(Provide epidemiologic or resource use data)*:
Mechanical ventilation is an essential, life-saving therapy for patients with critical illness and respiratory failure. Studies have estimated that more than 300,000 patients receive mechanical ventilation in the United States each year [1, 2]. These patients are at high risk for complications and poor outcomes, including death [1-4]. Ventilator-associated pneumonia (VAP), sepsis, Acute Respiratory Distress Syndrome (ARDS), pulmonary embolism, barotrauma, and pulmonary edema are among the complications that can occur in patients receiving mechanical ventilation; such complications can lead to longer duration of mechanical ventilation, ICU and hospital stay, increased costs, and increased risk of disability and death. Mortality in patients with acute lung injury on mechanical ventilation has been estimated to range from 24% in patients ages 15-19 years to 60% for patients 85 years and older [3].

Surveillance for ventilator-associated events in the National Healthcare Safety Network (NHSN) has to date been limited to VAP. One report estimated that there are more than 50,000 VAPs per year in the United States, at a cost of as much as $25,072 per patient (2005 dollars) [5].

However, there is currently no gold standard, valid, reliable definition for VAP, and even the most widely-used VAP criteria and definitions (including the NHSN definitions used in the previously-endorsed NQF measure #0140, Ventilator-associated pneumonia for ICU and high-risk nursery patients) are neither sensitive nor specific [6-9]. A major difficulty with current VAP definitions is that they rely on radiographic findings of pneumonia. Evidence suggests that chest radiograph findings do not accurately identify VAP. The subjectivity and variability inherent in chest radiograph technique, interpretation, and reporting, make chest imaging ill-suited for inclusion in a definition algorithm to be used for the potential purposes of public reporting, inter-facility comparisons, and pay-for-reporting and pay-for-performance programs. Furthermore, some of the most effective measures for improving outcomes of patients on mechanical ventilation do not specifically target VAP prevention [10, 11]. Therefore, a different approach is proposed: surveillance for ventilator-associated events (VAEs). The proposed VAE measures, which are based on objective, streamlined, and potentially automatable definitions (and which do not include chest radiograph findings), will address a broad range of conditions and complications occurring in mechanically-ventilated adult patients [12].

It is essential to have objective, reliable surveillance definitions for use in public reporting, inter-facility comparisons, and federal pay-for-performance and pay-for-reporting programs.

Preliminary data indicate that streamlined, objective algorithms to detect ventilator-associated complications are easily implemented, can make use of electronic health record systems to automate event detection, and identify events that are clinically important and associated with outcomes such as ICU and hospital length of stay and mortality [12].

1a.4 **Citations for Evidence of High Impact cited in 1a.3:** 1) Behrendt CE. Acute respiratory failure in the United States*: incidence and 31-day survival. Chest 2000;118:1100-5.
2) Kahn JM, Goss CH, Heagerty PJ, et al. Hospital volume and the outcomes of mechanical ventilation. N Engl J Med 2006;355:41-50.
3) Rubenfeld GD, Caldwell E, Peabody E, et al. Incidence and outcomes of acute lung injury. N Engl J Med 2005;353:1685-93.
4) Esteban A, Anzueto A, Frutos F, et al. Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. JAMA 2002;287:345-55.
5) http://www.cdc.gov/HAI/pdfs/hai/Scott_CostPaper.pdf , accessed 13 December 2011.
6) Klompas M. Does this patient have ventilator-associated pneumonia? JAMA 2007;297:1583-93.
7) Klompas M. Interobserver variability in ventilator-associated pneumonia surveillance. Am J Infect Control 2010;38:237-9.
8) Klompas M, Kulldorff M, Platt R. Risk of misleading ventilator-associated pneumonia rates with use of standard clinical and microbiological criteria. Clin Infect Dis 2008;46:1443-6.
9) Zilberberg MD, Shorr AF. Ventilator-associated pneumonia: the clinical pulmonary infection score as a surrogate for diagnostics and outcome. Clin Infect Dis 2010;51 Suppl 1:S131-5.
10) Girard T, Kress JP, Fuchs BD, et al. Efficacy and safety of a paired sedation and ventilator weaning protocol for mechanically-ventilated patients in intensive care (Awakening and Breathing Controlled trial): a randomised controlled trial. Lancet 2008;371:126-34.
11) Strom T, Martinussen T, Toft P. A protocol of no sedation for critically ill patients receiving mechanical ventilation. Lancet 2010;375:475-80.
12) Klompas M, Khan Y, Kleinman K, et al. Multicenter evaluation of a novel surveillance paradigm for complications of mechanical

ventilation. PLoS One 2011;6:e18062.

1b. Opportunity for Improvement: H☐ M☐ L☐ I☐
(*There is a demonstrated performance gap - variability or overall less than optimal performance*)

1b.1 Briefly explain the benefits (improvements in quality) envisioned by use of this measure:
It is anticipated that the proposed VAE measures will provide healthcare facilities with an objective, reliable, and efficient way to assess progress in improving the care and outcomes of patients on mechanical ventilation. Through use of the proposed measures, effective prevention strategies can be identified and promoted.

1b.2 Summary of Data Demonstrating Performance Gap *(Variation or overall less than optimal performance across providers)*:
[*For Maintenance* – *Descriptive statistics for performance results for this measure - distribution of scores for measured entities by quartile/decile, mean, median, SD, min, max, etc.*]
The proposed VAE surveillance definition algorithm represents a new approach to improving the safety of patients on mechanical ventilation. There are currently no data on VAEs (VAC and IVAC) to demonstrate a performance gap.

However, we may be able to draw some conclusions from NHSN VAP data, which show that rates of VAP vary across patient location types and according to healthcare facility teaching status and unit bed size [1].

Investigators have also shown that outcomes of patients on mechanical ventilation are significantly better in hospitals with high case volume than in those with lower case volume [2], after adjustment for factors such as patient severity of illness, age, comorbid conditions, preadmission location and length of stay, and hospital teaching status, geographic region, and ICU intensivist staffing.

These related data suggest that there is highly likely to be a performance gap for VAEs, as defined by the algorithm included in this proposal.

1b.3 Citations for Data on Performance Gap: [*For Maintenance* – *Description of the data or sample for measure results reported in 1b.2 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]
1) Dudeck MA, Horan TC, Peterson KD, et al. National Healthcare Safety Network (NHSN) Report, data summary for 2010, device-associated module. Am J Infect Control 2011;39:798-816.
2) Kahn JM, Goss CH, Heagerty PJ, et al. Hospital volume and the outcomes of mechanical ventilation. N Engl J Med 2006;355:41-50.
3) Esteban A, Anzueto A, Frutos F, et al. Characteristics and outcomes in adult patients receiving mechanical ventilation: a 28-day international study. JAMA 2002;287:345-55.

1b.4 Summary of Data on Disparities by Population Group: [*For Maintenance* –*Descriptive statistics for performance results for this measure by population group*]
As above, the VAE algorithm upon which this proposal is based represents a new approach, and as such, there are currently no data to show disparities by population group.

However, if we consider the 2010 NHSN data summary, rates of VAP (which may be considered a type of VAE) range from 0 events per 1000 ventilator days in respiratory intensive care units (ICUs) and pediatric medical wards to 6.0 events per 1000 ventilator days in trauma ICUs [1].

Kahn et al. showed that patients on mechanical ventilation in a high-volume hospital (>400 patients receiving mechanical ventilation per year) had an adjusted in-hospital mortality of approximately 25.5%, as compared to 34.2% in patients on mechanical ventilation in a low-volume hospital (<=150 patients receiving mechanical ventilation per year) (adjusted odds ratio for death 0.66, 95% confidence interval: 0.52 to 0.83, p<0.001) [2].

In an international, multicenter, prospective cohort study of mechanically-ventilated, critically-ill adults, Esteban, et al., showed that several factors were independent predictors of mortality, including patient age, severity of illness at ICU admission, coma as the reason for initiation of mechanical ventilation, and several factors related to patient management during mechanical ventilation [3].

These data suggest that rates of VAEs are highly likely to vary widely among certain patient populations or types of ICUs and facilities.

1b.5 Citations for Data on Disparities Cited in 1b.4: [*For Maintenance** – Description of the data or sample for measure results reported in 1b.4 including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*]

1) Dudeck MA, Horan TC, Peterson KD, et al. National Healthcare Safety Network (NHSN) Report, data summary for 2010, device-associated module. Am J Infect Control 2011;39:798-816.
2) Kahn JM, Goss CH, Heagerty PJ, et al. Hospital volume and the outcomes of mechanical ventilation. N Engl J Med 2006;355:41-50.

1c. Evidence (*Measure focus is a health outcome OR meets the criteria for quantity, quality, consistency of the body of evidence.*)
Is the measure focus a health outcome?   Yes☐ No☐   __If not a health outcome__, rate the body of evidence.

Quantity: H☐ M☐ L☐ I☐   Quality: H☐ M☐ L☐ I☐   Consistency: H☐ M☐ L☐ I☐

Quantity	Quality	Consistency	Does the measure pass subcriterion1c?
M-H	M-H	M-H	Yes☐
L	M-H	M	Yes☐ IF additional research unlikely to change conclusion that benefits to patients outweigh harms: otherwise **No**☐
M-H	L	M-H	Yes☐ IF potential benefits to patients clearly outweigh potential harms: otherwise **No**☐
L-M-H	L-M-H	L	No ☐

Health outcome – rationale supports relationship to at least one healthcare structure, process, intervention, or service	Does the measure pass subcriterion1c? Yes☐ IF rationale supports relationship

1c.1 Structure-Process-Outcome Relationship (*Briefly state the measure focus, e.g., health outcome, intermediate clinical outcome, process, structure; then identify the appropriate links, e.g., structure-process-health outcome; process- health outcome; intermediate clinical outcome-health outcome*):
VAE (VAC and IVAC) SIRs are new health outcome measures that have limited field experience to date; however, there is ample reason to expect that they are relevant to at-risk patient populations because prevention recommendations for these patients have been published to reduce the incidence of selected VAEs, such as VAP.

Prevention bundles for mechanically-ventilated patients have also been developed (see http://.ihi.org/knowledge/Pages/Changes/ImplementtheVentilatorBundle.aspx) and endorsed (see http://www.qualityforum.org/Measures_List.aspx?#k=ventilator+bundle). A high VAC or IVAC SIR represents an opportunity for improvement.

1c.2-3 Type of Evidence (*Check all that apply*):
Clinical Practice Guideline, Selected individual studies (rather than entire body of evidence), Systematic review of body of evidence (other than within guideline development)

1c.4 Directness of Evidence to the Specified Measure (*State the central topic, population, and outcomes addressed in the body of evidence and identify any differences from the measure focus and measure target population*):
The VAE algorithm upon which this proposal is based represents a new approach to surveillance in mechanically-ventilated patients, and as such, there are currently no published guidelines that specifically address prevention of the universe of VAEs as defined in the proposed algorithm. VAEs may include pneumonia, pulmonary embolism, pulmonary edema, sepsis, etc. (see Klompas M, et al., PLoS One 2011;6:e18062).

However, there are published guidelines that are related to events or clinical conditions that may be detected by the proposed VAE algorithm. For example, there are published guidelines on sepsis management (see Dellinger RP, Levy MM, Carlet JM, et al. Surviving Sepsis Campaign: International guidelines for management of severe sepsis and septic shock. Crit Care Med 2008; [published correction appears in Crit Care Med 2008; 36:1394-1396] 36:296-327). There are also a variety of guidelines for the prevention of venous thromboembolism in different patient populations (including the following: Qaseem A, et al., Ann Intern Med 2011;155:625-32; and 2008 guidelines of the ACCP, available at http://chestjournal.chestpubs.org/content/133/6_suppl).

The current U.S.-based VAP prevention and management guidelines are listed below:

1)Tablan OC, Anderson LJ, Besser R, et al. Guidelines for preventing healthcare-associated pneumonia, 2003. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2004;53(RR03):1-36. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm .
2) Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med 2005;171:388-416.
3) Coffin SE, Klompas M, Classen D, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals. Society for Healthcare Epidemiology of America/Infectious Diseases Society of America Practice Recommendation. Infect Control Hosp Epidemiol 2008;29(S1):S31-40.

Note that there are other published VAP guidelines (e.g., from the European Union and Canada).

Bundles, such as the Institute for Healthcare Improvement (IHI) ventilator bundle, address best practices for clinical care of mechanically ventilated patients.

For the guidelines listed above, target populations vary, but frequently include critically ill patients or, in the case of VAP, critically ill patients on mechanical ventilation. This is the same target population for the proposed VAE measures. The VAE measures are intended to capture a range of conditions and complications affecting mechanically ventilated patients. The VAE measures will capture events characterized by a clinically-significant, sustained period of worsening oxygenation following a period of stability or improvement on the ventilator.

1c.5 **Quantity of Studies in the Body of Evidence** *(Total number of studies, not articles)*: There are numerous studies in the literature on prevention and management of specific types of adverse events (including VAP) in patients in the ICU and/or on mechanical ventilation (see above). Because the VAE algorithm represents a new approach to surveillance and identification of conditions or complications of mechanical ventilation, there are no studies or guidelines of which we are aware that specifically address prevention of VAEs as defined in the proposed algorithm.

There are, however, a few recent studies exploring alternative, objective definitions for VAP or ventilator-associated complications (VAC):

1) Klompas M, Khan Y, Kleinman K, et al. Multicenter evaluation of a novel surveillance paradigm for complications of mechanical ventilation. PLoS One 2011;6:e18062.
2) Klompas M, Kleinman K, Platt R. Development of an algorithm for surveillance of ventilator-associated pneumonia with electronic data and comparison of algorithm results with clinician diagnoses. Infect Control Hosp Epidemiol 2008;29:31-7.
3) Klompas M, Kleinman K, Kahn Y, et al. Rapid and reproducible surveillance for ventilator-associated pneumonia. Clin Infect Dis 2012;54:in press (expected online January 10, in print February 15).

There is one manuscript on alternative definitions that is in preparation for submission.

Three abstracts on the subject of alternative, objective VAP or VAC definitions were presented at the 2011 annual meeting of the Society for Healthcare Epidemiology of America (SHEA):

1) Lee G, Sandora TJ, Graham D, Thompson D, Choi S, Pappas A, Klompas M, Magill S, Priebe G, Potter-Bynoe G, Harper M. Redefining ventilator-associated pneumonia surveillance in pediatric facilities. Abstract #49, 21st Annual Scientific Conference of the Society for Healthcare Epidemiology of America, Dallas, TX, April 1-4, 2011.
   --This abstract explored performance of alternative definitions in pediatric and neonatal patient populations. It is not directly related to the current proposal, which is for adults only, but will inform future efforts to develop a similar, objective algorithm suitable for use in pediatric and neonatal patients.

2) Klompas M, Magill S, Robicsek A, Kleinman K, Evans RS, Lloyd JF, Yokoe DS, Khan Y, Stevenson K, Samore M, Platt R. Exploration and validation of potential objective definitions for ventilator-associated pneumonia. Abstract #382, 21st Annual Scientific Conference of the Society for Healthcare Epidemiology of America, Dallas, TX, April 1-4, 2011.

--This study evaluated various alternative definitions focused on worsening oxygenation in combination with objective signs of infection or inflammation (very similar to the definitions in the proposed VAE algorithm). Chest radiograph evidence was not included. Events detected by the objective, alternative definitions were significantly associated with increased length of stay and mortality. Event rates were also reasonable, and as high as 10 events per 1000 ventilator days (higher than most NHSN VAP rates reported by ICUs). Abstract available at: http://shea.confex.com/shea/2011/webprogram/Paper3770.html .

3) Ricks PM, Klompas M, Viray M, Hota B, Craver C, Canteen-Harbor C, Horan T, Magill S. Assessment of a draft streamlined ventilator-associated pneumonia definition: data collection burden, agreement with current National Healthcare Safety Network pneumonia definitions, and clinical relevance. Abstract #383, 21st Annual Scientific Conference of the Society for Healthcare Epidemiology of America, Dallas, TX, April 1-4, 2011.
--This project evaluated the burden associated with surveillance for events detected by an alternative VAP definition (similar to the definitions in the proposed VAE algorithm), and found it to be less than that associated with surveillance using the current NHSN VAP definitions. It also found that events detected by the alternative, streamlined definition were significantly associated with length of stay and mortality. Abstract available at: http://shea.confex.com/shea/2011/webprogram/Paper4111.html .

Because the target population for the proposed VAE measures is the same as that of the current VAP prevention guidelines, it may be useful to consider the quantity of evidence in the VAP literature. There are numerous published studies of prevention measures for VAP. The SHEA/IDSA guideline for prevention of VAP in acute care hospitals (see citation #3 in 1c.2, above) cites 138 published studies and other references. The HICPAC healthcare-associated pneumonia prevention guidelines (see citation #1 in 1c.2, above) includes 433 citations. A PubMed search for English language publications on "VAP prevention" (performed December 15, 2011) yielded 455 citations.

1c.6 Quality of Body of Evidence (*Summarize the certainty or confidence in the estimates of benefits and harms to patients across studies in the body of evidence resulting from study factors. Please address: a) study design/flaws; b) directness/indirectness of the evidence to this measure (e.g., interventions, comparisons, outcomes assessed, population included in the evidence); and c) imprecision/wide confidence intervals due to few patients or events*): There are currently no guidelines or body of literature on prevention of VAEs as defined in this proposal. Because the target populations are the same, it may be informative to consider the quality of the body of evidence on VAP prevention. This body of evidence is substantial, and yet limited by the lack of a gold standard, objective, reliable definition for VAP. For this reason, studies that utilize endpoints such as mortality, duration of mechanical ventilation, and duration of ICU and hospital stay (as opposed to incidence of VAP) are arguably more robust.

In a published study on outcomes associated with VAC (Klompas M, et al., PLoS One 2011;6:e18062), patients who met the VAC definition had significantly more days to extubation, days to ICU discharge, and days to hospital discharge than patients who did not meet the VAC definition. In addition, patients who met the VAC definition had significantly higher mortality than patients who did not meet the VAC definition. By contrast, when the current NHSN VAP definitions were assessed in this study, mortality was not significantly different in patients meeting the definitions as compared to those who did not meet the definitions.

There are currently no published studies evaluating prevention of events detected by the current measure proposal for VAEs. A study is underway in the CDC Prevention Epicenters (http://www.cdc.gov/HAI/epiCenters/index.html) to assess the responsiveness of VAEs to implementation of a prevention initiative using spontaneous awakening and breathing trials in mechanically ventilated patients.

1c.7 Consistency of Results across Studies *(Summarize the consistency of the magnitude and direction of the effect):* Currently there are no published studies evaluating prevention of events detected by the current measure proposal for VAEs. For VAP, consistency of results across studies depends on the specific prevention measure under study. There are a large number of measures that have been studied for VAP prevention.

1c.8 Net Benefit *(Provide estimates of effect for benefit/outcome; identify harms addressed and estimates of effect; and net benefit - benefit over harms)*:
Two prevention measures for which the data are more robust include evaluating mechanically-ventilated patients for eligibility for and performing (in eligible patients) spontaneous awakening and breathing trials. These prevention measures do not specifically target VAP--as the goal of these measures is reduction in the amount of time a patient is on a ventilator, performance of these prevention measures has the potential to reduce the occurrence of VAEs in general, including but not limited to VAP.

In a relatively recent randomized, controlled trial of spontaneous awakening and breathing trials to liberate patients from mechanical ventilation, investigators found that patients in the intervention arm had more days of unassisted breathing (difference of approximately 3 days), shorter ICU and hospital stays (differences of approximately 3.8 and 4.3 days, respectively), and a lower likelihood of dying than patients in the control arm (see Girard TD, et al., Lancet 2008;371:126-34).

1c.9 **Grading of Strength/Quality of the Body of Evidence**. Has the body of evidence been graded? Yes

1c.10 **If body of evidence graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias:** Because the proposed VAE measures represent a new approach, there is no body of evidence to grade at the present time. It may be informative to consider how the evidence has been rated for VAP, which can be considered one type of VAE.

In current U.S.-based guidelines, grading of evidence was performed as follows:

1) Tablan OC, Anderson LJ, Besser R, et al. Guidelines for preventing healthcare-associated pneumonia, 2003. Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee. MMWR 2004;53(RR03):1-36. Available at: http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5303a1.htm .

- In this CDC/HICPAC guideline, "each recommendation is categorized on the basis of existing scientific data, theoretical rationale, applicability, and economic impact."
- Rating of the evidence is done as follows:
    --Category IA. Strongly recommended for implementation and strongly supported by well-designed experimental, clinical, or epidemiologic studies.
    --Category IB. Strongly recommended for implementation and supported by certain clinical or epidemiologic studies and by strong theoretical rationale.
    --Category IC. Required for implementation, as mandated by federal or state regulation or standard.
    --Category II. Suggested for implementation and supported by suggestive clinical or epidemiologic studies or by strong theoretical rationale.
    --No recommendation; unresolved issue. Practices for which insufficient evidence or no consensus exists about efficacy.

2) Guidelines for the management of adults with hospital-acquired, ventilator-associated, and healthcare-associated pneumonia. American Thoracic Society and Infectious Diseases Society of America. Am J Respir Crit Care Med 2005;171:388-416.

- Evidence rated as follows:
    --Level I (high): Evidence comes from well conducted, randomized controlled trials
    --Level II (moderate): Evidence comes from well designed, controlled trials without randomization (including cohort, patient series, and case-control studies). Level II studies also include any large case series in which systematic analysis of disease patterns and/or microbial etiology was conducted, as well as reports of new therapies that were not collected in a randomized fashion
    --Level III (low): Evidence comes from case studies and expert opinion. In some instances therapy recommendations come from antibiotic susceptibility data without clinical observations.

3) Coffin SE, Klompas M, Classen D, et al. Strategies to prevent ventilator-associated pneumonia in acute care hospitals. Society for Healthcare Epidemiology of America/Infectious Diseases Society of America Practice Recommendation. Infect Control Hosp Epidemiol 2008;29(S1):S31-40.

- Strength of evidence rated as follows (see Section 4 of guidelines):
    --A: Good evidence to support a recommendation for use
    --B: Moderate evidence to support a recommendation for use
    --C: Poor evidence to support a recommendation

- Quality of evidence rated as follows:
    --I: Evidence from at least 1 properly randomized, controlled trial

--II: Evidence from at least 1 well-designed clinical trial, without randomization; from cohort or case-control analytic studies (preferably from >1 center); from multiple time series; or from dramatic results from uncontrolled experiments.
    --III: Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees
Note. (Adapted from the Canadian Task Force on the Periodic Health Examination)

1c.11 System Used for Grading the Body of Evidence: Other

1c.12 If other, identify and describe the grading scale with definitions: See above, in 1c.10.

1c.13 Grade Assigned to the Body of Evidence: Grade depends upon the specific prevention measure. This is not applicable to the proposed VAE measures. In addition, there is not one single summary grade assigned to the entire body of VAP prevention literature.

1c.14 Summary of Controversy/Contradictory Evidence: Not applicable to the proposed VAE measures at the present time. There are a number of controversial issues in VAP prevention, many of which may arise because of the fundamental challenge in accurately and reliably defining VAP as an outcome measure.

1c.15 Citations for Evidence other than Guidelines *(Guidelines addressed below)*:
See 1c.5.

1c.16 Quote verbatim, <u>the specific guideline recommendation</u> *(Including guideline # and/or page #)*:
See 1c.10.

There are no published guidelines for prevention of VAEs (VACs and IVACs), as defined in the current proposal.

1c.17 Clinical Practice Guideline Citation: See 1c.10.

There are no published guidelines for prevention of VAEs (VACs and IVACs), as defined in the current proposal.

1c.18 National Guideline Clearinghouse or other URL: http://www.guideline.gov/content.aspx?id=13396&search=ventilator-associated+pneumonia (for reference #3 above)

1c.19 Grading of Strength of Guideline Recommendation. Has the recommendation been graded? Yes

1c.20 If guideline recommendation graded, identify the entity that graded the evidence including balance of representation and any disclosures regarding bias: See 1c.10.

1c.21 System Used for Grading the Strength of Guideline Recommendation: Other

1c.22 If other, identify and describe the grading scale with definitions: See 1c.10.

1c.23 Grade Assigned to the Recommendation: There is no single summary grade assigned to the body of VAP prevention measures.

1c.24 Rationale for Using this Guideline Over Others: There is no guideline for the prevention of VAEs as defined in the current measure proposal. For published VAP guidelines, the URL for the IDSA/SHEA guideline is provided above in 1c.18 because it is at this time the most recent of the 3 published guidelines.

Based on the NQF descriptions for rating the evidence, what was the <u>developer's assessment</u> of the quantity, quality, and consistency of the body of evidence?
1c.25 Quantity: Moderate   1c.26 Quality: Moderate 1c.27 Consistency: Moderate

Was the threshold criterion, *Importance to Measure and Report*, met?
(***1a & 1b must be rated moderate or high and 1c yes***) Yes ☐ No ☐

Provide rationale based on specific subcriteria:

For a new measure if the Committee votes NO, then STOP.
For a measure undergoing endorsement maintenance, if the Committee votes NO because of 1b. (no opportunity for improvement), it may be considered for continued endorsement and all criteria need to be evaluated.

2. RELIABILITY & VALIDITY - SCIENTIFIC ACCEPTABILITY OF MEASURE PROPERTIES

Extent to which the measure, as specified, produces consistent (reliable) and credible (valid) results about the quality of care when implemented. (evaluation criteria)
Measure testing must demonstrate adequate reliability and validity in order to be recommended for endorsement. Testing may be conducted for data elements and/or the computed measure score. Testing information and results should be entered in the appropriate field. Supplemental materials may be referenced or attached in item 2.1. See guidance on measure testing.

S.1 **Measure Web Page** *(In the future, NQF will require measure stewards to provide a URL link to a web page where current detailed specifications can be obtained)*. Do you have a web page where current detailed specifications for this measure can be obtained? No

S.2 **If yes, provide web page URL:**

2a. RELIABILITY. Precise Specifications and Reliability Testing: H☐ M☐ L☐ I☐

2a1. Precise Measure Specifications. (*The measure specifications precise and unambiguous.*)

2a1.1 **Numerator Statement** *(Brief, narrative description of the measure focus or what is being measured about the target population, e.g., cases from the target population with the target process, condition, event, or outcome)*:
VAC: Total number of observed healthcare-associated VACs among adult patients in acute and long-term acute care hospitals and inpatient rehabilitation facilities

IVAC: Total number of observed healthcare-associated IVACs among adult patients in acute and long-term acute care hospitals and inpatient rehabilitation facilities

2a1.2 **Numerator Time Window** *(The time period in which the target process, condition, event, or outcome is eligible for inclusion)*:
Cases are included if they are healthcare-associated, as defined below, and their event dates are during a month in which the patient care area (location) participated in NHSN surveillance for Ventilator-Associated Events. It will be necessary to have a data sample of sufficient size to generate meaningful SIRs; thus, the SIRs will be based on data for an entire calendar year.

2a1.3 **Numerator Details** *(All information required to identify and calculate the cases from the target population with the target process, condition, event, or outcome such as definitions, codes with descriptors, and/or specific data collection items/responses*:
I. Definitions of VAC and IVAC:

Step 1: Patient has a baseline period of stability or improvement on the ventilator, defined by >= 2 calendar days of stable or decreasing fraction of inspired oxygen (FiO2) or positive end expiratory pressure (PEEP). Baseline FiO2 and PEEP are defined by the minimum daily FiO2 or PEEP measurement during the period of stability or improvement.

Step 2: After a period of stability or improvement on the ventilator, the patient has at least one of the following indicators of worsening oxygenation:

-Minimum daily FiO2 values increase >= 0.20 (20 points) over baseline and remain at or above that increased level for >= 2 calendar days
-Minimum daily PEEP values increase >= 3 cmH2O over baseline and remain at or above that increased level for >= 2 calendar days

If Steps 1 and 2 are met, then a Ventilator-Associated Condition (VAC) has been detected.

Step 3: On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening

oxygenation, the patient meets both of the following criteria:

- Temperature > 38 °C or < 36°C, OR white blood cell count >= 12,000 cells/mm3 or <= 4,000 cells/mm3

AND

- A new antimicrobial agent(s) is started, and is continued for >= 4 calendar days.

If Steps 1, 2 and 3 are met, then an Infection-related Ventilator-Associated Complication (IVAC) has been detected.

II. Definition of healthcare-associated: There must be no evidence that the condition was present or incubating at the time of admission to the care setting. A patient must have been mechanically ventilated for at least four days to be able to meet the required VAE criteria.

III. Definition of mechanical ventilator support: Use of a mechanical device to assist or control respiration continuously, inclusive of the weaning period, through a tracheostomy or by endotracheal intubation (see http://www.cdc.gov/nhsn/PDFs/pscManual/6pscVAPcurrent.pdf). This does not include receiving rescue mechanical ventilation therapy. Rescue mechanical ventilation therapies that are excluded from VAE surveillance include: high frequency ventilation, mechanical ventilation in the prone position, and extracorporeal membrane oxygenation.

IV. CDC location: A CDC-defined designation given to a patient care area housing patients who have similar disease conditions or who are receiving care for similar medical or surgical specialties. Each facility location that is monitored is "mapped" to a CDC location. The specific CDC location code is determined by the type of patients cared for in that area according to the 80% Rule. That is, if 80% of patients are of a certain type (e.g., adult patients with orthopedic problems) then that area is designated as that type of location (in this case, an Inpatient Adult Orthopedic Ward).

V. Location: The patient care area to which a patient is assigned while receiving care in the healthcare facility.

VI. Location of attribution: The inpatient location where the patient was assigned on the date of the VAC or IVAC event, which is further defined as the date when the first clinical evidence appeared.

VII. Date of event: The date when the first signs or symptoms of a VAC or IVAC (clinical evidence) appeared.

VIII. Facility-specific data for individual patient locations (i.e., bed size of location, affiliation and level of affiliation with a medical school based on teaching status: major, graduate, limited, not affiliated) -
- Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services.
- Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships).
- Limited: Hospital is used in the medical school's teaching program to only a limited extent.

2a1.4 Denominator Statement *(Brief, narrative description of the target population being measured)*:
VAC: Total number of expected VACs, calculated by multiplying the number of ventilator days for each location under surveillance for VAEs during the period by the VAC rate for the same types of locations obtained from the standard population.

IVAC: Total number of expected IVACs, calculated by multiplying the number of ventilator days for each location under surveillance for VAEs during the period by the IVAC rate for the same types of locations obtained from the standard population.

2a1.5 Target Population Category *(Check all the populations for which the measure is specified and tested if any)*: Adult/Elderly Care, Maternal Care, Populations at Risk, Special Healthcare Needs

2a1.6 Denominator Time Window *(The time period in which cases are eligible for inclusion)*:
The number of ventilator days for the location under surveillance for VAEs during the period is collected. This number is multiplied by the standard population's VAC and IVAC rates for the same type of location to obtain the number of expected VACs and IVACs, respectively. The expected number of VACs and IVACs is the sum of VACs and IVACs, respectively, across all location types

during the period. The expected number of VACs and IVACs will be influenced by the number of ventilator days in the facility and the rates in the standard population. It is necessary to have a data sample of sufficient size to generate meaningful SIR; thus, the SIRs will be based on data for an entire calendar year.

2a1.7 Denominator Details (*All information required to identify and calculate the target population/denominator such as definitions, codes with descriptors, and/or specific data collection items/responses*):
1. Number of ventilator days for locations under VAE surveillance during the period. For each location under VAE surveillance, the number of patients on mechanical ventilation is collected daily, at the same time each day during the month. The ventilator day totals for each month will be entered into NHSN.
2. VAC and IVAC rate per 1000 ventilator days for the same location types from the identified population.
3. See 2a1.3 for definitions of CDC location, location, and location of attribution.
4. See 2a1.3 for definition of facility-specific data for individual patient locations.

2a1.8 Denominator Exclusions *(Brief narrative description of exclusions from the target population)*:
Patients receiving non-conventional (rescue) mechanical ventilation therapies are excluded. Rescue mechanical ventilation therapies that are excluded from VAC and IVAC surveillance include (but are not limited to) the following: high-frequency mechanical ventilation, mechanical ventilation in the prone position, and extracorporeal membrane oxygenation.

2a1.9 Denominator Exclusion Details *(All information required to identify and calculate exclusions from the denominator such as definitions, codes with descriptors, and/or specific data collection items/responses)*:
See 2a1.8.

2a1.10 Stratification Details/Variables *(All information required to stratify the measure results including the stratification variables, codes with descriptors, definitions, and/or specific data collection items/responses)*:
1. CDC location: A CDC-defined designation given to a patient care area housing patients who have similar disease conditions or who are receiving care for similar medical or surgical specialties. Each facility location that is monitored is "mapped" to a CDC location. The specific CDC location code is determined by the type of patients cared for in that area according to the 80% Rule. That is, if 80% of patients are of a certain type (e.g., adult patients with orthopedic problems) then that area is designated as that type of location (in this case, an Inpatient Adult Orthopedic Ward).
2. Facility-specific data for individual patient locations (i.e., bed size of location, affiliation and level of affiliation with a medical school based on teaching status: major, graduate, limited, not affiliated) -
- Major: A hospital that is an important part of the teaching program of a medical school and the majority of medical students rotate through multiple clinical services.
- Graduate: Hospital is used by the medical school for graduate trainings only (residency and/or fellowships).
- Limited: Hospital is used in the medical school's teaching program to only a limited extent.

2a1.11 Risk Adjustment Type *(Select type. Provide specifications for risk stratification in 2a1.10 and for statistical model in 2a1.13)*: Stratification by risk category/subgroup   **2a1.12 If "Other," please describe:**

2a1.13 Statistical Risk Model and Variables *(Name the statistical method - e.g., logistic regression and list all the risk factor variables. Note - risk model development should be addressed in 2b4.)*:
SIR is an indirect standardization method for summarizing healthcare-associated event experience across any number of stratified groups of data. VAC and IVAC incidence rates will be stratified by patient care location and in some instances, location bed size and type of medical school affiliation. Example: expected numbers of VACs (and VAC rates) in an adult burn critical care unit are not the same as in an adult long-term acute care (LTAC) unit.

2a1.14-16 Detailed Risk Model Available at Web page URL (or attachment). Include coefficients, equations, codes with descriptors, definitions, and/or specific data collection items/responses. Attach documents only if they are not available on a webpage and keep attached file to 5 MB or less. NQF strongly prefers you make documents available at a Web page URL. Please supply login/password if needed:
URL
Not applicable--no such URL.
Not applicable.

2a1.17-18. **Type of Score:** Ratio

2a1.19 **Interpretation of Score** *(Classifies interpretation of score according to whether better quality is associated with a higher score, a lower score, a score falling within a defined interval, or a passing score)*: Better quality = Lower score

2a1.20 **Calculation Algorithm/Measure Logic***(Describe the calculation of the measure score as an ordered sequence of steps including identifying the target population; exclusions; cases meeting the target process, condition, event, or outcome; aggregating data; risk adjustment; etc.)*:
The SIR is calculated as follows:
1. Identify the number of VACs/IVACs in each location type;
2. Total these numbers for an observed number of VACs or IVACs;
3. Obtain the number of expected number of VACs/IVACs in the same location types for the standard population;
4. Identify the number of expected VACs/IVACs for the facility based on its location types and numbers of ventilator days:
  a. For each location type, multiply the number of ventilator days   experienced, by the expected VAC/IVAC rate for that location;
  b. Sum the number of expected VACs/IVACs from all locations.
5. Divide the total number of observed VAC/IVAC events ("2" above) by the "expected" number of VAC/IVAC events.
6. Result = SIR.

Note: The standard population is anticipated to be the population under surveillance for VAEs during the first year of VAE surveillance implementation in NHSN (estimated to be calendar year 2013-2014).

Note: The NHSN analysis tool will perform the calculations once the patient event data and denominator information are entered into the system.

2a1.21-23 **Calculation Algorithm/Measure Logic Diagram URL or attachment:**
Attachment
VAE SIR Calculation Algorithm.docx

2a1.24 **Sampling (Survey) Methodology.** If measure is based on a sample (or survey), provide instructions for obtaining the sample, conducting the survey and guidance on minimum sample size (response rate):
Measure is not based on sampling or survey.

2a1.25 **Data Source** *(Check all the sources for which the measure is specified and tested)*. If other, please describe:
 Electronic Clinical Data, Electronic Clinical Data : Electronic Health Record, Electronic Clinical Data : Laboratory, Electronic Clinical Data : Pharmacy, Paper Records

2a1.26 **Data Source/Data Collection Instrument** (*Identify the specific data source/data collection instrument, e.g. name of database, clinical registry, collection instrument, etc.*): Numerator and denominator data collection forms for NHSN Ventilator-Associated Events (VAEs) are being developed.

2a1.27-29 **Data Source/data Collection Instrument Reference Web Page URL or Attachment:** URL
Not available at the present time.
Not applicable.

2a1.30-32 **Data Dictionary/Code Table Web Page URL or Attachment:**
URL
Under development and not available at the present time.
Not applicable.

2a1.33 **Level of Analysis** (*Check the levels of analysis for which the measure is specified and tested)*: Facility, Population : National, Population : State

2a1.34-35 **Care Setting** *(Check all the settings for which the measure is specified and tested)*: Hospital/Acute Care Facility, Other:Long term acute care, Post Acute/Long Term Care Facility : Rehabilitation

2a2. Reliability Testing. (*Reliability testing was conducted with appropriate method, scope, and adequate demonstration of reliability.*)

2a2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
The standard population's VAC and IVAC rates that will be used in the SIR calculations will be from acute care hospitals (14 different types of adult ICUs), long-term acute care hospitals, and inpatient rehabilitation facilities reporting to NHSN. It is possible to make VAE data sample estimations based on current reporting of VAP rates to NHSN. There are data to show that VAC rates may be higher than NHSN VAP rates (Klompas M, et al. PLoS One 2011;6:e18062). The VAP event numerators from adult critical care locations in 2010 ranged from 0 to 555 VAP events submitted to NHSN, and the denominators ranged from 6,659 to 358,913 ventilator days, with 8 of 14 adult ICU locations having more than 100,000 ventilator days (Dudeck MA, et al. Am J Infect Control 2011;39:798-816). Therefore, we anticipate that for most critical care locations, the standard population's rates will be robust enough to use for determining the expected number of VACs and IVACs.

2a2.2 Analytic Method *(Describe method of reliability testing & rationale)*:
The SIR is identical in concept to a standardized mortality ratio (SMR) and summarizes healthcare-associated event experience across any number of stratified groups of data using indirect standardization. The SMR is a widely accepted method of measurement within the public health community. The SIR is deemed a methodologically sound measure for VAC and IVAC experiences within facilities because it:
1) provides a single measure that is simple to interpret for assessing VAC/IVAC incidence problems and prevention efficacy, and
2) gives a better estimate of the event experience when there are small numerators or denominators in some or all strata.

2a2.3 Testing Results *(Reliability statistics, assessment of adequacy in the context of norms for the test conducted)*:
Although the proposed measure represents a novel surveillance approach in NHSN for VAEs, the current NHSN VAP measure has previously been endorsed by NQF. The proposed VAC and IVAC measures represent a marked improvement upon the current NHSN VAP measure in terms of the objectivity and simplicity of the criteria utilized in the event definitions. Published data show that interobserver reliability of the current NHSN VAP definitions is suboptimal (kappa 0.40, Klompas M, et al. Am J Infect Control 2010;38:237-9). We anticipate, based in part on unpublished and preliminary data, that the interobserver reliability of the proposed VAC/IVAC definitions will be high. In addition, there is the potential to automate VAC/IVAC surveillance, which is currently not possible using the NHSN VAP definitions.

We and our collaborators are currently undertaking studies to assess the reliability of the proposed VAC/IVAC definitions as well as their preventability using established best practices and their association with important clinical outcomes.

2b. VALIDITY. Validity, Testing, <u>including all Threats to Validity</u>:   H☐ M☐ L☐ I☐

2b1.1 Describe how the measure specifications *(measure focus, target population, and exclusions)* **are consistent with the evidence cited in support of the measure focus (***criterion 1c***) and identify any differences from the evidence:**
The proposed VAC/IVAC measures focus more broadly on conditions or complications occurring in mechanically-ventilated patients. They do not seek to specifically identify VAP, since there is currently no valid, reliable VAP definition in use for clinical care, research or public health purposes.

2b2. Validity Testing. (*Validity testing was conducted with appropriate method, scope, and adequate demonstration of validity.*)

2b2.1 Data/Sample *(Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Although it is not possible to determine whether the proposed VAC and IVAC measures are valid measures of VAP (since there is no gold standard VAP definition), studies are underway to address whether events detected by the proposed VAC and IVAC definitions are associated with more clinically-important and robust outcomes, such as length of stay and mortality.

2b2.2 Analytic Method *(Describe method of validity testing and rationale; if face validity, describe systematic assessment)*:
Studies are underway. Related work has already been performed and published (see Klompas M, et al. PLoS One 2011;6:e18062).

2b2.3 Testing Results *(Statistical results, assessment of adequacy in the context of norms for the test conducted; if face validity, describe results of systematic assessment)*:
See the following reference: Klompas M, et al. PLoS One 2011;6:e18062. Also, note that the proposed VAC/IVAC definition

algorithm was developed by a Working Group composed of representatives from several key professional societies and organizations, including member societies of the Critical Care Societies Collaborative. A key concern of the Working Group in developing the proposed surveillance definition algorithm was the face validity or clinical credibility of the definitions.

POTENTIAL THREATS TO VALIDITY. (*All potential threats to validity were appropriately tested with adequate results.*)

2b3. Measure Exclusions. (*Exclusions were supported by the clinical evidence in 1c or appropriately tested with results demonstrating the need to specify them.*)

2b3.1 Data/Sample for analysis of exclusions (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):
Patients in whom respiratory support devices are used that do not meet the NHSN definition of a ventilator will be excluded. Patients receiving rescue mechanical ventilation therapies will also be excluded, due to the relatively limited experience with patients receiving these therapies and the lack of comparability of patients receiving these therapies to patients receiving conventional mechanical ventilation. Rescue therapies include (but are not limited to) high frequency ventilation, extracorporeal membrane oxygenation and mechanical ventilation in the prone position.

2b3.2 Analytic Method (*Describe type of analysis and rationale for examining exclusions, including exclusion related to patient preference*):
Exclusions were based on the existing NHSN ventilator definition (which also applies to the current NHSN VAP definitions, previously endorsed by NQF, i.e., Ventilator-associated pneumonia for ICU and high-risk nursery [HRN] patients) as well as the expert opinion of the Working Group representatives.

2b3.3 Results (*Provide statistical results for analysis of exclusions, e.g., frequency, variability, sensitivity analyses):*
No results available.

2b4. Risk Adjustment Strategy. (*For outcome measures, adjustment for differences in case mix (severity) across measured entities was appropriately tested with adequate results.*)

2b4.1 Data/Sample (*Description of the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included*):
The standard population's VAC and IVAC rates that will be used in the SIR calculations will be from adult ICUs (14 different types), long-term acute care hospitals, and inpatient rehabilitation facilities. It is possible to make VAE data sample estimations based on current reporting of VAP rates to NHSN. There are data to show that VAC rates may be higher than NHSN VAP rates (Klompas M, et al. PLoS One 2011;6:e18062). The VAP event numerators from adult critical care locations in 2010 ranged from 0 to 555 VAP events submitted to NHSN, and the denominators ranged from 6,659 to 358,913 ventilator days, with 8 of 14 adult ICU locations having more than 100,000 ventilator days (Dudeck MA, et al. Am J Infect Control 2011;39:798-816). Therefore, we anticipate that for most critical care locations, the standard population's rates will be robust enough to use for determining the expected number of VACs and IVACs.

2b4.2 Analytic Method (*Describe methods and rationale for development and testing of risk model or risk stratification including selection of factors/variables*):
The SIR is the ratio of the observed number of VACs or IVACs to the expected number of VACs or IVACs. VAC/IVAC rates per 1000 ventilator days, which are used to calculate the expected number of VACs/IVACs for the denominator of the SIR, are indirectly standardized rates accounting for the influence of length of stay and length of ventilator use, and are stratified by patient care location, which adjusts for differences in patient morbidity and disease-specific variables which may influence VAC/IVAC risk. If the number of VACs/IVACs that is observed is the same as the number expected for a patient care location of that type and size, then the SIR will = 1.0. If the number of observed events is less than the number expected for a patient care location of that type and size, then the SIR will be less than 1.0. Likewise, if the number of observed events is more than the number expected for a patient care location of that type and size, then the SIR will be greater than 1.0 (e.g., an SIR of 2.0 represents a location that has observed twice the number of expected events for that location type).

2b4.3 Testing Results (*Statistical risk model: Provide quantitative assessment of relative contribution of model risk factors; risk model performance metrics including cross-validation discrimination and calibration statistics, calibration curve and risk decile plot, and assessment of adequacy in the context of norms for risk models. Risk stratification: Provide quantitative assessment of relationship of risk factors to the outcome and differences in outcomes among the strata*):

Not applicable at this time.

2b4.4 If outcome or resource use measure is not risk adjusted, provide rationale and analyses to justify lack of adjustment: There is insufficient evidence to support risk adjustment of VAC/IVAC rates beyond the stratification by CDC location type (and in some cases by unit size and academic affiliation) that is currently performed in NHSN (as noted in 2a1.10). The Working Group has identified this as a key research agenda item to be addressed in the next 1-2 years.

2b5. Identification of Meaningful Differences in Performance. (*The performance measure scores were appropriately analyzed and discriminated meaningful differences in quality.*)

2b5.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
SIRs have been used as metrics for summarizing HAI experience in individual states for other NHSN-related measures.

2b5.2 Analytic Method *(Describe methods and rationale to identify statistically significant and practically/meaningfully differences in performance)*:
The SIR by nature identifies variation from an expected rate of occurrence of an event and a sense of the magnitude of that variation, e.g., a facility VAC SIR of 2.0 represents twice as many VACs as expected for the patient population. Additionally, the confidence interval provides further information regarding the likelihood that the SIR occurs within a specified range.

2b5.3 Results *(Provide measure performance results/scores, e.g., distribution by quartile, mean, median, SD, etc.; identification of statistically significant and meaningfully differences in performance)*:
 The VAC and IVAC SIRs and 95% confidence intervals will be calculated and graphically represented to show the relationship to the nominal value of 1.0 (i.e., where observed equals expected).

2b6. Comparability of Multiple Data Sources/Methods. (*If specified for more than one data source, the various approaches result in comparable scores.*)

2b6.1 Data/Sample *(Describe the data or sample including number of measured entities; number of patients; dates of data; if a sample, characteristics of the entities included)*:
Not applicable.

2b6.2 Analytic Method *(Describe methods and rationale for testing comparability of scores produced by the different data sources specified in the measure)*:
Not applicable.

2b6.3 Testing Results *(Provide statistical results, e.g., correlation statistics, comparison of rankings; assessment of adequacy in the context of norms for the test conducted)*:
Not applicable.

2c. Disparities in Care: H☐ M☐ L☐ I ☐ NA☐ (*If applicable, the measure specifications allow identification of disparities.*)

2c.1 If measure is stratified for disparities, provide stratified results *(Scores by stratified categories/cohorts)*: Not applicable.

2c.2 If disparities have been reported/identified (e.g., in 1b), but measure is not specified to detect disparities, please explain:
Not applicable.

2.1-2.3 Supplemental Testing Methodology Information:
URL
None to be submitted.
Not applicable.

Steering Committee: Overall, was the criterion, *Scientific Acceptability of Measure Properties*, met?
(***Reliability and Validity must be rated moderate or high***) Yes☐   No☐
Provide rationale based on specific subcriteria:

If the Committee votes No, STOP

3. USABILITY

Extent to which intended audiences (e.g., consumers, purchasers, providers, policy makers) can understand the results of the measure and are likely to find them useful for decision making. (**evaluation criteria**)

C.1 **Intended Purpose/ Use** *(Check all the purposes and/or uses for which the measure is intended)*:   Public Health/Disease Surveillance, Public Reporting, Quality Improvement (Internal to the specific organization), Quality Improvement with Benchmarking (external benchmarking to multiple organizations)

3.1 **Current Use** *(Check all that apply; for any that are checked, provide the specific program information in the following questions)*:   Public Reporting, Public Health/ Disease Surveillance, Quality Improvement with Benchmarking (external benchmarking to multiple organizations), Quality Improvement (Internal to the specific organization), Not in use

3a. Usefulness for Public Reporting: H☐ M☐ L☐ I☐
(*The measure is meaningful, understandable and useful for public reporting.*)

3a.1. **Use in Public Reporting - disclosure of performance results to the public at large** *(If used in a public reporting program, provide name of program(s), locations, Web page URL(s)).* If not publicly reported in a national or community program, state the reason AND plans to achieve public reporting, potential reporting programs or commitments, and timeline, e.g., within 3 years of endorsement: [*For Maintenance – If not publicly reported, describe progress made toward achieving disclosure of performance results to the public at large and expected date for public reporting; provide rationale why continued endorsement should be considered.*]
The VAE definition algorithm has not yet been implemented for use in the National Healthcare Safety Network, but we anticipate that it will be implemented in 2013. It was developed specifically with the potential purpose of public reporting in mind.

Regarding the VAC and IVAC SIR measures, it is important to note that the SMR is a widely accepted measurement tool within the public health community and the SIR is but a variation on this method.

The SIR has been available and used by NHSN member facilities for HAI surveillance since 2005 and in NNIS facilities before that. The Centers for Disease Control and Prevention published several reports in 2010 on HAIs. SIRs for individual U.S. states were published in May 2011 on the NHSN website at http://www.cdc.gov/nhsn/index.html :

1) State-Specific Supplement to the National Healthcare-Associated Infection Standardized Infection Ratio Report: July 2009 through December 2009 National HAI Standardized Infection Ratio (SIR), Report, July-December 2009.

2) State-Specific HAI Standardized Infection Ratio (SIR), Report, January-June 2009.

Additional reports are scheduled for publication in early 2012. A precedent has been set for using SIRs for public reporting of HAIs by several states. Such states include Pennsylvania (report may be found at http://www.portal.health.state.pa.us/portal/server.pt/community/department_of_health_home/1745), Tennessee (report may be found at http://health.state.tn.us/Downloads/TN_HAI_Report_2008_Jan_Dec_final.pdf), and South Carolina (http://www.scdhec.gov/health/disease/hai/reports.htm).

3a.2. **Provide a rationale for why the measure performance results are meaningful, understandable, and useful for public reporting**. If usefulness was demonstrated (e.g., focus group, cognitive testing), describe the data, method, and results: The SIR provides a means for comparing a specific facility-location rate against a standard facility-location rate, as opposed to simply providing the facility's crude event rate:
- SIR<1, the facility-location has a lower infection or event rate than the average (mean) facility-location.
- SIR>1, the facility-location has a higher infection or event rate than the average (mean) facility-location.
- SIR=1, the facility-location has an infection or event rate equal to that of the average (mean) facility-location.

3.2 **Use for other Accountability Functions (payment, certification, accreditation).** If used in a public accountability program, provide name of program(s), locations, Web page URL(s): Not applicable.

3b. Usefulness for Quality Improvement: H☐ M☐ L☐ I☐

(*The measure is meaningful, understandable and useful for quality improvement.*)

3b.1. Use in QI. If used in quality improvement program, provide name of program(s), locations, Web page URL(s):
[*For <u>Maintenance</u> – If not used for QI, indicate the reasons and describe progress toward using performance results for improvement*].
In 2010, more than 800 facilities reported VAP events during at least one month of the year. The new VAE definition algorithm has not yet been deployed for use in NHSN, but once implemented, we expect facility uptake to equal or exceed that for VAP. Through built-in analytical tools, we anticipate facilities will be able to calculate their own location-specific VAC and IVAC SIRs, just as they are able to calculate SIRs for other NHSN-related events.

3b.2. Provide rationale for why the measure performance results are meaningful, understandable, and useful for quality improvement. <u>If usefulness was demonstrated</u> *(e.g., QI initiative),* describe the data, method and results:
The SIR provides a means for a facility to compare either its total or location-specific infection or event rates against a national mean.
- SIR<1, the facility-location has a lower infection or event rate than the average (mean) facility-location.
- SIR>1, the facility-location has a higher infection or event rate than the average (mean) facility-location.
- SIR=1, the facility-location has an infection or event rate equal to that of the average (mean) facility-location.

Combined with the SIR, facilities can use the crude event rates to assess changes in rates and effectiveness of control measures.

Overall, to what extent was the criterion, *Usability*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

4. FEASIBILITY

Extent to which the required data are readily available, retrievable without undue burden, and can be implemented for performance measurement. **(evaluation criteria)**

4a. Data Generated as a Byproduct of Care Processes: H☐ M☐ L☐ I☐

4a.1-2 How are the data elements needed to compute measure scores generated? *(Check all that apply).*
Data used in the measure are:
generated by and used by healthcare personnel during the provision of care, e.g., blood pressure, lab value, medical condition

4b. Electronic Sources: H☐ M☐ L☐ I☐

4b.1 Are the data elements needed for the measure as specified available electronically *(Elements that are needed to compute measure scores are in defined, computer-readable fields)*: Some data elements are in electronic sources

4b.2 If ALL data elements are not from electronic sources, specify a credible, near-term path to electronic capture, OR provide a rationale for using other than electronic sources: Not all healthcare facilities have electronic data capture of key elements of the proposed measures' definitions: fraction of inspired oxygen (FiO2), positive end expiratory pressure (PEEP), temperature, white blood cell counts, and treatment with a new antimicrobial agent. We do not expect all facilities or even a substantial proportion of healthcare facilities will have this capability prior to the proposed introduction of this measure in 2013. However, these data elements are captured as part of routine patient care in mechanically-ventilated patients and could be transferred, either manually or electronically, to a spreadsheet that would allow facilities to easily identify patients that meet the VAC or IVAC definitions. Furthermore, we anticipate that in the coming years, healthcare facilities will increasingly have the ability to capture some or all of the VAC and IVAC data elements electronically, thereby facilitating automation of event detection.

4c. Susceptibility to Inaccuracies, Errors, or Unintended Consequences: H☐ M☐ L☐ I☐

4c.1 Identify susceptibility to inaccuracies, errors, or unintended consequences of the measurement identified during testing and/or operational use and strategies to prevent, minimize, or detect. If audited, provide results:
Patient medical records and other sources of patient data must be reviewed to determine if the patient meets the necessary criteria for a healthcare-associated VAC/IVAC. It is possible that reviewers may miss objective findings in electronic or paper medical records, or fail to identify that patients meet criteria, thereby underreporting VAC/IVAC events. Data collectors might also intentionally underreport VAC/IVAC events. Both of these actions would result in an SIR that is calculated to be lower than actual.

Alternatively, patients may be identified as having a VAC/IVAC when in fact they do not meet the definition criteria and thereby calculate an SIR that is higher than actual. In addition, it is possible SIRs may be miscalculated. The NHSN reporting tool will include business logic to minimize misclassification of VAC/IVAC events and inaccurate reporting of ventilator days. In addition, site visits can be conducted to audit data validity and this has been done for other infection types by some of the states using NHSN as their mandatory reporting tool (for example, see New York's audit process summary: http://www.health.state.ny.us/statistics/facilities/hospital/hospital_acquired_infections/2008/docs/hospital-acquired_infection.pdf , p20).

As the VAC and IVAC definitions are substantially more objective and streamlined than current NHSN VAP definitions, we anticipate that under- and over-reporting of events due to errors in data collection will be minimized.

4d. Data Collection Strategy/Implementation: H☐ M☐ L☐ I☐

A.2 Please check if either of the following apply (*regarding proprietary measures*):
4d.1 Describe what you have learned/modified as a result of testing and/or operational use of the measure regarding data collection, availability of data, missing data, timing and frequency of data collection, sampling, patient confidentiality, time and cost of data collection, other feasibility/implementation issues (*e.g., fees for use of proprietary measures*):
We have learned through our own work and the work of our collaborators that collection of the required data elements in the VAE definition algorithm appears to be substantially less burdensome and more reliable than collection of data elements currently required in the NHSN VAP definitions. The proposed definition algorithm is amenable to electronic event detection and reporting as well, in contrast to the current NHSN VAP definitions.

Overall, to what extent was the criterion, *Feasibility*, met? H☐ M☐ L☐ I☐
Provide rationale based on specific subcriteria:

OVERALL SUITABILITY FOR ENDORSEMENT

Does the measure meet all the NQF criteria for endorsement? Yes☐ No☐
Rationale:

If the Committee votes No, STOP.
If the Committee votes Yes, the final recommendation is contingent on comparison to related and competing measures.

5. COMPARISON TO RELATED AND COMPETING MEASURES

If a measure meets the above criteria and there are endorsed or new related measures (either the same measure focus or the same target population) or competing measures (both the same measure focus and the same target population), the measures are compared to address harmonization and/or selection of the best measure before a final recommendation is made.

5.1 If there are related measures *(either same measure focus or target population)* or competing measures *(both the same measure focus and same target population)*, list the NQF # and title of all related and/or competing measures:
0140 : Ventilator-associated pneumonia for ICU and high-risk nursery (HRN) patients

5a. Harmonization

5a.1 If this measure has EITHER the same measure focus OR the same target population as NQF-endorsed measure(s):
Are the measure specifications completely harmonized? No

5a.2 If the measure specifications are not completely harmonized, identify the differences, rationale, and impact on interpretability and data collection burden:
Not applicable. The previously endorsed NHSN VAP measure (NQF measure #0140) is not well-suited to use in the current environment of public reporting and benchmarking of healthcare-associated events and will be retired. Therefore there are no related or competing measures of which we are aware.

5b. Competing Measure(s)

5b.1 If this measure has both the same measure focus and the same target population as NQF-endorsed measure(s):
Describe why this measure is superior to competing measures (*e.g., a more valid or efficient way to measure quality*); OR

provide a rationale for the additive value of endorsing an additional measure. *(Provide analyses when possible)*:
Not applicable. CDC plans to retire measure #0140.

CONTACT INFORMATION

Co.1 Measure Steward (Intellectual Property Owner): Centers for Disease Control and Prevention, 1600 Clifton Road, MS A-24, Atlanta, Georgia, 30333

Co.2 Point of Contact: Daniel, Pollock, MD, dap1@cdc.gov, 404-639-4237-

Co.3 Measure Developer if different from Measure Steward: Centers for Disease Control and Prevention, 1600 Clifton Road, MS A-24, Atlanta, Georgia, 30333

Co.4 Point of Contact: Daniel, Pollock, MD, dap1@cdc.gov, 404-639-4237-

Co.5 Submitter: Daniel, Pollock, MD, dap1@cdc.gov, 404-639-4237-, Centers for Disease Control and Prevention

Co.6 Additional organizations that sponsored/participated in measure development:
Critical Care Societies Collaborative—Society of Critical Care Medicine, American Association of Critical Care Nurses, American Thoracic Society, American College of Chest Physicians

Society for Healthcare Epidemiology of America

Infectious Diseases Society of America

Association of Professionals in Infection Control and Epidemiology

Council of State and Territorial Epidemiologists

Healthcare Infection Control Practices Advisory Committee (HICPAC) Surveillance Working Group

DHHS Office of Healthcare Quality

National Institutes of Health

CDC Prevention Epicenters

Co.7 Public Contact: Daniel, Pollock, MD, dap1@cdc.gov, 404-639-4237-, Centers for Disease Control and Prevention

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ADDITIONAL INFORMATION

Workgroup/Expert Panel involved in measure development
Ad.1 Provide a list of sponsoring organizations and workgroup/panel members' names and organizations. Describe the members' role in measure development.
The proposed VAE definition algorithm was developed by CDC's VAP Surveillance Definition Working Group, and was based upon work performed by Dr. Michael Klompas and collaborators in the CDC Prevention Epicenters.

Working Group participation is as follows:

Critical Care Societies Collaborative—Society of Critical Care Medicine (representatives: Dr. Clifford Deutschman, Dr. Marin Kollef, Dr. Pamela Lipsett); American Association of Critical-Care Nurses (representatives: Ms. Suzanne Burns, Ms. Beth Hammer); American Thoracic Society (representatives: Dr. Nicholas Hill, Dr. Mitchell Levy); American College of Chest Physicians (representatives: Dr. Robert Balk, Dr. David Gutterman);

Society for Healthcare Epidemiology of America (representative: Dr. Michael Klompas);

Infectious Diseases Society of America (representative: Dr. Edward Septimus);

Association of Professionals in Infection Control and Epidemiology (representative: Ms. Linda Greene);

Council of State and Territorial Epidemiologists (representative: Ms. Carole VanAntwerpen);

Healthcare Infection Control Practices Advisory Committee (HICPAC) Surveillance Working Group (representative: Dr. Daniel Diekema);

DHHS Office of Healthcare Quality (participant: Dr. Don Wright);

National Institutes of Health (participant: Dr. David Henderson);

CDC Prevention Epicenters investigators.

Ad.2 If adapted, provide title of original measure, NQF # if endorsed, and measure steward. Briefly describe the reasons for adapting the original measure and any work with the original measure steward: Not applicable.

Measure Developer/Steward Updates and Ongoing Maintenance
Ad.3 Year the measure was first released: 2011
Ad.4 Month and Year of most recent revision: 12, 2011
Ad.5 What is your frequency for review/update of this measure? Annually and as needed.
Ad.6 When is the next scheduled review/update for this measure? 09, 2012

Ad.7 Copyright statement:

Ad.8 Disclaimers:

Ad.9 Additional Information/Comments:

Date of Submission (*MM/DD/YY*): 01/12/2012

NQF Measure Proposal Submission 1861: National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure

Attachment for 2a1.21: Calculation Algorithm/Measure Logic Diagram for Ventilator-Associated Events (VAEs)

LOCATION TYPE	a Number of OBSERVED IVACs*	b Total Number of Ventilator Days	c 2013 IVAC rate/1,000 (pooled mean all U.S. facilities)	b X c /1000 Number of EXPECTED IVACs
Burn Critical Care	4	600	10.7	6.42
Medical Cardiac Critical Care	4	1700	2.1	3.57
Medical Critical Care—Major	12	2810	2.2	6.182
Neurologic Critical Care	2	255	6.7	1.7085
Neurosurgical Critical Care	5	660	5.3	3.498
Pediatric Medical Critical Care	1	1500	2.3	3.45
Pediatric Medical/Surgical Critical Care	8	3110	1.8	5.598
Surgical Critical Care	15	1800	4.9	8.82
Trauma Critical Care	11	1300	8.1	10.53
TOTAL	**62**	**N/A**	**N/A**	**49.78**

*In this example, the VAE under surveillance is Infection-related Ventilator-Associated Complication (IVAC).

Note: Data are presented for illustration purposes only.

SIR   **62/49.78 = 1.25**