Developing a New, National Approach to Surveillance for Ventilator-Associated Events: Executive Summary

Shelley S. Magill,¹ Michael Klompas,^{2,3,4} Robert Balk,^{5,6} Suzanne M. Burns,^{6,7} Clifford S. Deutschman,^{6,8} Daniel Diekema,^{9,10} Scott Fridkin,¹ Linda Greene,^{11,12} Alice Guh,¹ David Gutterman,^{6,13} Beth Hammer,^{6,14} David Henderson,¹⁵ Dean Hess,^{16,17,18} Nicholas S. Hill,^{6,19} Teresa Horan,¹ Marin Kollef,^{6,20} Mitchell Levy,^{6,21} Edward Septimus,^{22,23} Carole VanAntwerpen,^{24,25} Don Wright,²⁶ and Pamela Lipsett^{6,27}

¹Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, Atlanta, Georgia; ²Department of Population Medicine, Harvard Medical School and Harvard Pilgrim Health Care Institute, Boston, Massachusetts; ³Infection Control Department, Brigham and Women's Hospital, Boston, Massachusetts; ⁴Society for Healthcare Epidemiology of America, Arlington, Virginia; ⁵Division of Pulmonary and Critical Care Medicine, Rush University School of Medicine, Chicago, Illinois; ⁶Critical Care Societies Collaborative—American Association of Critical-Care Nurses, American College of Chest Physicians, American Thoracic Society, Society of Critical Care Medicine; ⁷School of Nursing, Critical and Acute Care, University of Virginia, Charlottesville, Virginia; ⁸Department of Anesthesiology and Critical Care, Perelman School of Medicine at the University of Pennsylvania, Philadelphia, Pennsylvania; ⁹Division of Infectious Diseases, University of Iowa Carver College of Medicine, Iowa City, Iowa; ¹⁰Healthcare Infection Control Practices Advisory Committee Surveillance Working Group, Atlanta, Georgia; ¹¹Infection Prevention and Control Department, Rochester General Health System, Rochester, New York; ¹²Association for Professionals in Infection Control and Epidemiology, Washington, District of Columbia; ¹³Department of Medicine, Medical College of Wisconsin, Milwaukee, Wisconsin; ¹⁴Department of Cardiology, Zablocki VA Medical Center, Milwaukee, Wisconsin; ¹⁵Hospital Epidemiology and Quality Improvement, The Clinical Center, National Institutes of Health, Bethesda, Maryland; ¹⁶Department of Respiratory Care, Massachusetts General Hospital, Boston, Massachusetts; ¹⁷Department of Anesthesia, Harvard Medical School, Boston, Massachusetts; ¹⁸American Association for Respiratory Care, Irving, Texas; ¹⁹Division of Pulmonary and Critical Care Medicine, Tufts Medical Center, Boston, Massachusetts; ²⁰Division of Pulmonary and Critical Care Medicine, Washington University, St. Louis, Missouri; ²¹Division of Pulmonary, Critical Care, and Sleep, Warren Alpert Medical School at Brown University, Rhode Island Hospital, Providence, Rhode Island; ²²Department of Internal Medicine, Texas A&M Health Science Center, College Station, Texas; ²³Infectious Diseases Society of America, Arlington, Virginia; ²⁴New York State Department of Health, Bureau of Healthcare-Associated Infections, Albany, New York; ²⁵Council of State and Territorial Epidemiologists, Atlanta, Georgia; ²⁶Office of Disease Prevention and Health Promotion, U.S. Department of Health and Human Services, Washington, District of Columbia; and ²⁷Department of Surgery, Anesthesiology and Critical Care Medicine, Johns Hopkins University School of Medicine, Baltimore, Maryland

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In September 2011, the Centers for Disease Control and Prevention (CDC) convened a Ventilator-Associated Pneumonia (VAP) Surveillance Definition Working Group to organize a formal process for leaders and experts of key stakeholder organizations to discuss the challenges of VAP surveillance definitions and to propose new approaches to VAP surveillance in adult

patients (Table 1). The charges to the Working Group were to:

1. Critically review a draft, streamlined VAP surveillance definition developed for use in adult patients;
2. Suggest modifications to enhance the reliability and credibility of the surveillance definition within the critical care and infection prevention communities;
3. Propose a final adult surveillance definition algorithm, to be implemented in the CDC's National Healthcare Safety Network (NHSN), taking into consideration the potential future use of the definition algorithm in public reporting, interfacility comparisons, and pay-for-reporting and pay-for-performance programs.

The Working Group's surveillance definition algorithm, which is referred to as the ventilator-associated

Correspondence: Shelley S. Magill, MD, PhD, Division of Healthcare Quality Promotion, Centers for Disease Control and Prevention, 1600 Clifton Road, MS A-24, Atlanta, GA 30329 (smagill@cdc.gov).

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Table 1. Ventilator-Associated Pneumonia Surveillance Definition Working Group Organizations, Representatives, and Federal Participants

Organization	Representative(s)
American Association of Critical Care Nurses	Suzanne Burns and Beth Hammer
American Association for Respiratory Care	Dean Hess
American College of Chest Physicians	Robert Balk and David Guterman
American Thoracic Society	Nicholas Hill and Mitchell Levy
Association of Professionals in Infection Control and Epidemiology	Linda Greene
Council of State and Territorial Epidemiologists	Carole VanAntwerpen
Healthcare Infection Control Practices Advisory Committee Surveillance Working Group	Daniel Diekema
Infectious Diseases Society of America	Edward Septimus
Society for Healthcare Epidemiology of America	Michael Klompas
Society of Critical Care Medicine	Clifford Deutschman, Marin Kollef, and Pamela Lipsett
U.S. Department of Health and Human Services, Office of Disease Prevention and Health Promotion	Don Wright
National Institutes of Health	David Henderson
Centers for Disease Control and Prevention, Division of Healthcare Quality Promotion	Scott Fridkin, Alice Guh, Shelley Magill, Teresa Horan, others

events or VAE surveillance definition algorithm, represents a purposeful departure from VAP toward more general, objective measures of conditions and complications occurring in patients on mechanical ventilation (Figure 1; VAE surveillance protocol available at: <http://www.cdc.gov/nhsn/acute-care-hospital/vae/index.html>). The VAE surveillance definition algorithm uses a tiered approach, moving from measures of ventilator-associated conditions (VAC), to infection-related ventilator-associated complications (IVAC), to possible and probable VAP.

The first tier of VAE surveillance, VAC, seeks to identify episodes of sustained respiratory deterioration, and will capture both infectious and non-infectious conditions and complications occurring in mechanically ventilated patients. VAC is defined by a sustained period of worsening oxygenation that immediately follows a baseline period of stability or improvement on the ventilator. To meet the VAC definition, a mechanically ventilated patient must have at least 2 calendar days of stable or decreasing daily minimum positive end-expiratory pressure (PEEP) or fraction of inspired oxygen (F_{IO_2}), followed by at least 2 days of increased daily minimum PEEP or F_{IO_2} , where the increase in the daily minimum PEEP is ≥ 3 cm H₂O

greater than the daily minimum PEEP during the baseline period, or where the increase in the daily minimum F_{IO_2} is ≥ 0.20 (or 20 percentage points in oxygen concentration) greater than the daily minimum F_{IO_2} during the baseline period. For example, if a patient's daily minimum F_{IO_2} requirement on days 4 and 5 of mechanical ventilation is 0.40, then the patient's daily minimum F_{IO_2} requirement would need to be at least 0.60 on days 6 and 7 of mechanical ventilation for the VAC definition to be met. The Working Group's decisions to set specific thresholds of 3 cm H₂O and 0.20 (20 points) for the increases in PEEP and F_{IO_2} , respectively, and to define a "sustained" increase as an increase persisting for at least 2 calendar days, were based on expert opinion of what criteria would likely identify clinically important events, while minimizing inadvertent inclusion of other types of events resulting in transient changes in oxygenation—such as surgery or performance of other procedures. Thresholds were also selected based upon published data indicating that increases of ≥ 2.5 cm H₂O in PEEP or ≥ 0.15 (15 points) in F_{IO_2} sustained for at least 2 days were associated with longer duration of mechanical ventilation, ICU and hospital stays, and increased mortality [1]. Subsequently, additional data have been published that support the Working Group's approach to VAC [2].

The second tier, IVAC, attempts to identify the subset of VACs that are potentially related to infection, as evidenced by an abnormal white blood cell count or temperature and initiation of a new antimicrobial agent. IVAC will likely capture patients with pulmonary infections and extrapulmonary infections of sufficient severity to trigger respiratory deterioration. The Working Group recognized the low predictive value of an abnormal temperature or white blood cell count in ICU patients, and Klompas and colleagues have shown that the addition of fever or abnormal white blood cell count to VAC definition does not substantially enhance the definition's predictive value for death [2]. Nevertheless, these are objective and readily available signs that are frequently used at the bedside to assess for the presence of infection. The additional required criterion of starting a new antimicrobial, where the new agent is continued for at least 4 days, may add specificity and clinical credibility to the IVAC definition, although data are needed.

The third tier, possible and probable VAP, attempts to zero in on the subset of IVAC patients with respiratory infections, as manifested by objective evidence of purulent respiratory secretions (where purulence is defined using quantitative or semi-quantitative criteria for the number of neutrophils on Gram stain) and/or positive results of microbiological tests performed on respiratory tract specimens. The possible VAP definition is met with the presence of purulent secretions or a positive lower respiratory tract culture (showing any growth); the probable VAP definition requires purulent secretions in addition to a positive lower respiratory tract culture meeting certain quantitative or

Figure 1. Ventilator-associated events surveillance definition algorithm*. *(Available at: <http://www.cdc.gov/nhsn/acute-care-hospital/vae/index.html>). Abbreviations: PEEP, positive end-expiratory pressure; F_{IO_2} , fraction of inspired oxygen; VAP, ventilator-associated pneumonia; CFU, colony-forming units.

semiquantitative thresholds of pathogen growth. Organisms that are uncommonly regarded as true VAP pathogens are excluded from possible and probable VAP culture criteria (with the exception of lung tissue cultures): *Candida* spp., coagulase-negative

staphylococci, and *Enterococcus* spp. The probable VAP definition can also be met based upon the presence of a positive pleural fluid culture, lung tissue with histopathological evidence of infection, or positive diagnostic tests for *Legionella* or selected respiratory

tract viruses, without the concomitant requirement for purulent secretions. Although data have shown that requiring purulent secretions or positive cultures in patients who have met a VAC definition actually diminishes the association between mortality and VAC [2], the Working Group felt that it was important to provide definitions within the VAE algorithm that more closely resemble VAP diagnostic criteria used at the bedside.

This tiered approach is believed to be the most appropriate approach in the current environment. It acknowledges limitations in the ability to accurately identify VAP for surveillance purposes—simply labeling an event “VAP” does not make it so—and focuses instead on a more general measure of complications of mechanical ventilation. This approach may also reduce the likelihood of definition gaming or manipulation that could artificially lower event rates.

Two features of the VAE surveillance definition algorithm are of particular note. First, radiographic evidence of pneumonia is not included as a criterion in any tier of the algorithm because of lack of specificity, and the subjectivity inherent in facilities’ and individual providers’ practices in ordering, performing, interpreting and reporting results of chest radiographs. Second, only VAC and IVAC (and therefore the overall VAE rate—the rate of all events meeting at least the VAC definition—and the rate of all events meeting at least the IVAC definition) are intended to be possible candidates for future use in public reporting, interfacility comparisons, and pay-for-performance programs. The VAC and IVAC definitions use criteria based on data anticipated to be available from most mechanically ventilated patients and less subject to manipulation or gaming. By contrast, the third definition tier, possible and probable VAP, was developed to be used only in internal quality improvement. These VAP definitions include criteria based on documentation of purulent secretions and/or microbiological findings and are more in keeping with traditional clinical constructs of VAP. Because of the substantial variability in the ordering and collection of lower respiratory tract specimens, and in laboratory processing of specimens and reporting of results, the Working Group determined that it was not appropriate to include these data elements in the VAC and IVAC definitions.

An iterative process for refining the definitions must be ensured as experience using the definition algorithm accumulates in the coming years. Although there was clearly a need to establish a new surveillance approach in the NHSN, there is also an urgent need to advance the science of surveillance for VAP and other VAE. The VAE surveillance definition algorithm should be studied, validated, and improved in an ongoing manner. Evaluation and refinement of the definitions should be conducted in collaboration with members of the Working Group and other members of stakeholder communities and organizations. The Working Group is already discussing potential modifications based on user feedback received during the first 3 months of VAE surveillance.

The VAP Surveillance Definition Working Group’s new approach to surveillance in mechanically ventilated adults acknowledges the current limitations in VAP diagnosis and the potential benefit in focusing surveillance on an objective, reliable, but more general measure of significant conditions and complications that occur in patients on ventilators. VAE surveillance was implemented by the CDC’s NHSN in January 2013. While much work remains, we believe this innovative approach to surveillance has significant potential to increase the validity of comparisons among healthcare facilities and, more importantly, to improve measurement and patient safety in the ICU.

Notes

Disclaimer. The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention, the American Association for Respiratory Care, the Association of Professionals in Infection Control and Epidemiology, the Council of State and Territorial Epidemiologists, or the Infectious Diseases Society of America.

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Ms Greene consults for INC. Dr Hess consulted for Philips Respironics, ResMed, Pari, and Breathe. Ms Greene lectured for Premier, Advanced Sterilization Products, and APIC. Dr Burns lectured for AACN (annual national conference). Ms Greene presented speeches for Covidien and Maquet. Dr Septimus received an honorarium for a lecture. Dr Klompas received support from the Society of Healthcare Epidemiologists of America for the development of educational presentations.

Ms Greene is employed by the Rochester General Hospital. Dr Lipsett has board membership with the Society of Critical Care Medicine. Dr Deutschman received a stipend for his Presidency with the Society of Critical Care Medicine.

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References

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, Magill S, Robicsek A, et al. Objective definitions for ventilator-associated pneumonia. *Crit Care Med* **2012**; 40:3154–61.