From VAP to VAE:
Establishing new definitions for Ventilator-Associated Events in Adults

Slides prepared by Mitchell M Levy, MD
Brown University

Presented by Suhail Raoof, MD
New York Methodist Hospital, NY

On behalf of the Critical Care Societies Collaborative (CCSC)
Ventilator-associated pneumonia (VAP) is an important complication of mechanical ventilation

- But other bad things also happen to patients on ventilators

No valid, reliable definition for VAP

- Need more accurate diagnostics ...
- Until those are available, how do we conduct surveillance and track prevention progress?

Commonly used definitions include subjective elements and are neither sensitive nor specific for VAP

- Not ideal in an era of public reporting of healthcare-associated infection (HAI) rates, comparisons among facilities, pay-for-performance programs

Need a new approach
NHSN Pneumonia (PNEU) Surveillance Definitions, 2002 to Present

- **Combination of x-ray, signs/symptoms and laboratory criteria**
  - Three sets of criteria
  - Chest imaging findings are required
  - Signs and symptoms of pneumonia are required
  - Laboratory evidence is optional—but should be used if available

- **To be “ventilator-associated”**
  - Endotracheal tube (ETT)/ventilator must have been in place at some time during the 48 hours preceding or at time of PNEU onset
  - **No required amount of time** that the ETT/ventilator must have been in place for a PNEU to count as a VAP

Limitations of Current VAP Definitions

- **Current definitions** (e.g., definitions used for surveillance in NHSN, Clinical Pulmonary Infection Score, European surveillance definitions, etc.) all use combinations of criteria:
  - **Chest x-ray**
    - Lack specificity for VAP\(^1\)
    - Interobserver variability\(^2\)
    - Not within purview of IP expertise
  - **Clinical signs/symptoms**
    - Lack sensitivity and specificity\(^3\)
    - Some are highly subjective
    - Documentation varies
  - **Microbiological evidence**
    - Lack sensitivity and specificity\(^4\)
    - Practices vary among providers
    - Controversy about best practices\(^5,6\)

References include but are not limited to the following:

- Fabregas N, et al., Thorax 1999;54:867-73
- Kirtland SH, et al., Chest 1997;112:445-57
- Berton DC, et al., Cochrane Database Syst Rev 2008
VAP Incidence Rates—All Reporting Facilities*

-13% (-13 to -14%)
-13% (-12 to -14%)
-16% (-15 to -17%)
-20% (-19 to -21%)

Analysis updated since abstract submission. Numbers may vary.
Why are VAP incidence rates declining?

- Evidence-based prevention measures
- Other reasons—several ways to lower VAP rates without improving patient care (Klompas et al., AJIC 2012;40:408-10)
  - Strict interpretation of clinical signs included in surveillance definitions
  - Strict interpretation of chest x-ray findings included in surveillance definitions
  - Requirement for consensus approach to VAP determinations or physician approval of cases
  - Practice of transferring out those patients needing prolonged mechanical ventilation
  - Admission of uncomplicated, vented post-operative patients to unit
Goals for Modifying Current Definitions

- Achieve face validity/clinical credibility
- Improve reliability
- Reduce burden
Working Group Objectives

- Critically **review** CDC’s draft, streamlined VAP surveillance definition for use in adult patients;
- Suggest **modifications** to enhance reliability and credibility within the critical care community;
- Propose final **adult definition** algorithm that will be **implemented** for use in NHSN for the potential future purposes of public reporting, inter-facility comparisons, and pay-for-performance programs.
“Ventilator-Associated Events” Surveillance Definition Algorithm—Tiered Approach

- **Tiers 1 and 2: Definitions suitable for potential use in public reporting**
  - Objective, general measures of Ventilator-Associated Conditions (VAC) and Infection-Related Complications (IVAC)
  - Definitions similar to Tier 1 VAC definition evaluated by Klompas et al. identified events associated with longer duration of mechanical ventilation, longer ICU stay, and increased mortality—and were more efficient to apply than current VAP definitions (*PLoS One* 2011;6:e18062, *Crit Care Med* 2012; in press)

- **Tier 3: Internal use definitions**
  - Possible VAP and Probable VAP, incorporating laboratory evidence

***Note that this is NOT a clinical definition algorithm and is not intended for use in the management of patients.***
Patients Eligible for VAE Surveillance

- ≥18 years of age
- Inpatients of acute care hospitals, long term acute care hospitals, inpatient rehabilitation facilities
- NOTE: Patients on high frequency ventilation or extracorporeal life support are EXCLUDED from VAE surveillance.
  - Patients who are receiving a conventional mode of mechanical ventilation while in the prone position, and patients who are receiving a conventional mode of mechanical ventilation while receiving nitric oxide therapy or epoprostenol therapy are INCLUDED.
  - Patients on Airway Pressure Release Ventilation (APRV) or related modes are INCLUDED, but VAC will be determined by changes in FiO$_2$ only, since changes in PEEP as indicated in this surveillance algorithm may not be applicable to APRV.
VAE Definition Algorithm Summary

- **Respiratory status component**
  - Patient on mechanical ventilation > 2 days
  - Baseline period of stability or improvement, followed by sustained period (>2 days) of worsening oxygenation

- **Infection / inflammation component**
  - Ventilator-Associated Condition (VAC)
    - General evidence of infection/inflammation
    - Infection-Related Ventilator-Associated Complication (IVAC)
      - Positive results of microbiological testing

- **Additional evidence**
  - Possible or Probable VAP

No CXR needed!
VAE Definition Algorithm Summary

Patient on mechanical ventilation > 2 days

Baseline period of stability or improvement, followed by sustained period of worsening oxygenation

Ventilator-Associated Condition (VAC)

General evidence of infection/inflammation

Infection-Related Ventilator-Associated Complication (IVAC)

Positive results of microbiological testing

Possible or Probable VAP
VAE Definition Algorithm Summary

- **Respiratory status component**
  - Patient on mechanical ventilation > 2 days
  - Baseline period of stability or improvement, followed by sustained period of worsening oxygenation

- **Infection / inflammation component**
  - General evidence of infection/inflammation
    - Infection-Related Ventilator-Associated Complication (IVAC)
      - Positive results of microbiological testing
        - Possible or Probable VAP

  - Temperature or WBC and New antimicrobial agent

- **Additional evidence**
Patient on mechanical ventilation > 2 days

Baseline period of stability or improvement, followed by sustained period of worsening oxygenation

Ventilator-Associated Condition (VAC)

General evidence of infection/inflammation

Infection-Related Ventilator-Associated Condition (IVAC)

Positive results of microbiological testing

Possible or Probable VAP

Purulent secretions and/or other positive laboratory evidence
VAE Definition Algorithm Summary

Ventilator-Associated Condition (VAC)

Infection-Related Ventilator-Associated Complication (IVAC)

Possible VAP or Probable VAP

Possible Future Public Reporting Definitions

Internal Quality Improvement
Tier 1: VAC

Patient has a baseline period of stability or improvement on the ventilator, defined by ≥ 2 calendar days of stable or decreasing daily minimum FiO₂ or PEEP values. The baseline period is defined as the two calendar days immediately preceding the first day of increased daily minimum PEEP or FiO₂.

AND

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

1) Increase in daily minimum FiO₂ of ≥ 0.20 (20 points) over the daily minimum FiO₂ in the baseline period, sustained for ≥ 2 calendar days.

2) Increase in daily minimum PEEP values of ≥ 3 cmH₂O over the daily minimum PEEP in the baseline period, sustained for ≥ 2 calendar days.
Tier 2: IVAC

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:

1) Temperature $> 38^\circ C$ or $< 36^\circ C$, OR white blood cell count $\geq 12,000$ cells/mm$^3$ or $\leq 4,000$ cells/mm$^3$.

AND

2) A new antimicrobial agent(s)* is started, and is continued for $\geq 4$ calendar days.

*See Appendix for eligible agents.
Tier 3: Possible VAP

Patient meets criteria for VAC and IVAC

AND

VAE Window Period

On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, ONE of the following criteria is met:

1) Purulent respiratory secretions (from one or more specimen collections)
   • Defined as secretions from the lungs, bronchi, or trachea that contain \( >25 \) neutrophils and \( <10 \) squamous epithelial cells per low power field [lpf, x100].
   • If the laboratory reports semi-quantitative results, those results must be equivalent to the above quantitative thresholds.

2) Positive culture (qualitative, semi-quantitative or quantitative) of sputum*, endotracheal aspirate*, bronchoalveolar lavage*, lung tissue, or protected specimen brushing*

*Excludes the following:
   • Normal respiratory/oral flora, mixed respiratory/oral flora or equivalent
   • *Candida* species or yeast not otherwise specified
   • Coagulase-negative *Staphylococcus* species
   • *Enterococcus* species
On or after calendar day 3 of mechanical ventilation and within 2 calendar days before or after the onset of worsening oxygenation, ONE of the following criteria is met:

1) Purulent respiratory secretions (from one or more sites defined as for possible VAP)

AND one of the following (see Table 2):

- Positive culture of endotracheal aspirate*, $\geq 10^5$ CFU/ml or equivalent semi-quantitative result
- Positive culture of bronchoalveolar lavage*, $\geq 10^4$ CFU/ml or equivalent semi-quantitative result
- Positive culture of lung tissue, $\geq 10^4$ CFU/g or equivalent semi-quantitative result
- Positive culture of protected specimen brush*, $\geq 10^3$ CFU/ml or equivalent semi-quantitative result

*Same organism exclusions as noted for Possible VAP.

2) One of the following (without requirement for purulent respiratory secretions):

- Positive pleural fluid culture (where specimen was obtained during thoracentesis or initial placement of chest tube and NOT from an indwelling chest tube)
- Positive lung histopathology
- Positive diagnostic test for *Legionella* spp.
- Positive diagnostic test on respiratory secretions for influenza virus, respiratory syncytial virus, adenovirus, parainfluenza virus, rhinovirus, human metapneumovirus, coronavirus
When will VAE surveillance be available in NHSN, and what is happening to PNEU/VAP?

- VAE available January 2013.
- In 2013, current VAP protocol will still be used for neonatal and pediatric patients ONLY.
  - Pediatric and Neonatal VAE Surveillance Definition Working Group kick-off meeting held on September 6, 2012
- In 2013, the current PNEU definitions will still be available for off-plan surveillance of VAP in adults or non-ventilated PNEU in adults or children.
Education, Training and Implementation

- NHSN application anticipated to be ready to accept VAE reports in late January 2013
- Working group report
- Multiple email communications, presentations and webinars—ATS, APIC, IDWeek, CHEST, etc.
- First “official” VAE training during 3-day NHSN training session at CDC, October 2012
  - Recorded version will be posted at [http://www.cdc.gov/nhsn/training/](http://www.cdc.gov/nhsn/training/)
- Surveillance protocol posted to the NHSN website:
- Worksheets and web-based VAE tool
Conclusions

- VAE represents new approach—focus on standardized methods, objectivity, reliability
- VAE will identify broad range of events in patients on mechanical ventilation, not limited to VAP
  - Requires thinking more broadly about prevention
- Key knowledge gaps
  - Preventability of events detected by VAE definition
  - Clinical correlates of IVAC, Possible and Probable VAP
  - Pediatric and neonatal VAE, other special populations?
  - Alternative modes of mechanical ventilation
  - Denominators
  - Risk adjustment or stratification