

# Editorial

## WHAT YOU CALL IT DOES MATTER: NEW DEFINITIONS OF ARDS AND VAP

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**T**wo of the most important pulmonary conditions in critical care are acute respiratory distress syndrome (ARDS) and ventilator-associated pneumonia (VAP). Each is associated with high mortality, increased health care costs, and significant long-term sequelae. Efforts to understand, prevent, diagnose, and treat these conditions are predicated on valid and reliable definitions. However, definitions for ARDS and VAP have been fraught with difficulty and imprecision. Recently, revised definitions for both conditions have been proposed. This will substantially affect critical care research and practice.

A definition is “a precise determination of the limits of anything, especially a disease process.”<sup>1</sup> Definitions circumscribe a condition, providing boundaries between what is and what is not its essential nature. However, clinical conditions exist in a complex environment where boundaries may be difficult to ascertain. Difficulty in determining these boundaries may arise because our current diagnostic processes lack sufficient detection ability. Determining precise boundaries is further complicated by the nature of clinical conditions. Many are syndromes: a collection of signs and symptoms described over the years. For centuries, there was little

else that medicine could do other than describe syndromes. Nonetheless, drawing boundaries and describing syndromes provides conceptual clarity necessary for both clinicians and researchers.

### Problems of Definition

Definitions of ARDS and VAP have been particularly resistant to delineation of distinct boundaries. The 1994 definition for ARDS by the American-European Consensus Conference (AECC) was developed to bring some uniformity to the previously disparate definitions for ARDS and has been widely used in research and clinical practice.<sup>2</sup> ARDS was defined as the severe manifestation of acute lung injury, characterized by the acute onset of hypoxemia, accompanied by bilateral infiltrates on chest radiography, without evidence of left atrial hypertension. Despite the improvements introduced by AECC, reliable application of the ARDS definition remained slippery. For example, no definition of “acute” was provided, and the effects of positive end-expiratory pressure (PEEP) on oxygenation were not considered in evaluation of hypoxemia. In 1994, measurement of pulmonary artery wedge pressure was routine in critically ill adults, and the definition included PAWP > 18 mm Hg as evidence of left atrial hypertension (ruling out ARDS by the 1994 definition).

Recently, the ARDS Definition Task Force was assembled by the European Society of Intensive Care

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Medicine to review and refine the 1994 AECC ARDS definition.<sup>3</sup> Following the creation of the draft “Berlin ARDS definition” (named for the site of the in-person discussions of the document), the international expert panel used a meta-analysis of existing data from multiple clinical trials to refine the definition further. The final Berlin definition thus benefited from both consensus among experts and validation with empirical data.

## Ventilator-Associated Pneumonia

The Centers for Disease Control and Prevention (CDC) has a particular interest in surveillance for health care acquired infections, including VAP. The VAP definition used by the CDC’s National Healthcare Safety Network (NHSN) has been in place since 2002.<sup>4</sup> It includes 2 required components (chest radiography, and signs and symptoms selected from multiple options) and optional laboratory findings. The current definition applies to mechanically ventilated patients without respect to how long the ventilator has been in place.

Noting that the current definition is complex and influenced by subjectivity, the CDC convened a VAP Surveillance Definition Working Group to revise the definition earlier this year.<sup>5</sup> The Critical Care Societies Collaborative participated in the working group, and the American Association of Critical-Care Nurses (AACN) was represented in the process by Suzanne Burns and Beth Hammer. The new surveillance definition algorithm is scheduled to be implemented in 2013.

The new CDC surveillance process has taken an interesting approach. Rather than focusing on VAP, the new surveillance definition algorithm for adults broadens the surveillance spectrum to ventilator-associated events (VAE). A ventilator-associated condition (VAC) is identified if, after a 3-day period of stability or improvement on the ventilator, the patient develops worsening oxygenation (specific increases in levels of  $\text{FiO}_2$  or PEEP over 2 or more calendar days).

Infection-related ventilator-associated complication (IVAC) is identified in patients with VAC who meet 2 additional criteria of having both clinical

signs of infection (specifically, defined values for an abnormal temperature or white count) and antibiotics prescribed for at least 4 days. Identification of possible and probable VAP within IVAC patients is determined by purulent respiratory secretions and/or specific laboratory and diagnostic tests. The new algorithm remains complex, and the CDC is developing additional guidance for its implementation.

Under the new VAE surveillance definition algorithm, VAC and IVAC are public reporting definitions. VAP cases are intended to be internally reported and used to guide quality improvement, rather than publicly reported.

Several features of the new VAE definition are important. First, chest radiographs, a required component in the current definition of VAP, are no longer used in the definition of VAEs (including VAP). Second, patients who are receiving rescue ventilation are excluded. Third, patients must have a period of at least 2 days of stability or improvement on mechanical ventilation prior to worsening. Fourth, VAC (and by extension, IVAC and VAP) is limited to patients who have been mechanically ventilated for at least 3 calendar days.

The additional specificity in inclusion and exclusion criteria, and the requirement for 2 calendar days of stability or improvement, will exclude some of the sickest patients in the ICU from surveillance. It is also likely to result in fewer identified cases of VAP than the current definition.

## The Use of Radiography

Chest radiographs have been problematic in the definition of ARDS and VAP. The ARDS Definition Task Force noted that interrater reliability of chest radiographs is poor. Severity on chest radiographs, when examined as an ancillary variable in the task force’s empirical tests, did not enhance the ARDS definition. The VAP Surveillance Definition Working Group expressed concerns regarding the accuracy of chest radiographs in VAP, and further concerns that variability in imaging, ordering, interpretation, and reporting limited their usefulness as a component of national surveillance definitions. Whereas the 2 groups agreed about the problems related to chest radiographs as definitional elements, they took divergent paths in their responses to those problems.

In the final Berlin definition, chest imaging is retained as an element, but is refined from the 1994 AECC definition. Imaging is expanded to include computed tomography scans as well as radiographs. Bilateral chest imaging opacities (unexplained by other causes) are included as an element of the

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Berlin ARDS definition; however, categorization of ARDS severity (mild, moderate, severe) is based on oxygenation status and not on chest imaging.

The VAP Surveillance Definition Working Group recommended removing chest radiography from the surveillance definition entirely, relying instead on data elements that have higher reliability, are more easily used in event detection, and can be more easily captured electronically.

## The Dangers of Definition

Examination of new definitions brings forward an important consideration: What purpose was intended for the definition? Neither the Berlin ARDS definition nor the NHSN VAE definition is intended to be used as a prognostic model. The Berlin ARDS definition was developed to improve consistency in clinical research and clinical practice.

A valid and reliable definition of ARDS is important in all phases of research, including selection of subjects, study design, outcome measures, and analytical strategies. Clinical trials of ARDS must be able to define groups of patients in categories of severity to determine whether specific therapies are beneficial, harmful, or ineffective for those groups. At the bedside, a valid and reliable ARDS definition enables providers to recognize the condition in an individual, respond with appropriate interventions, and judge improvement or deterioration.

The CDC NHSN definition of VAP (and now VAE, VAC, and IVAC) was developed to enable surveillance of an important event; the CDC specifically states that it should *not* be used for clinical diagnosis. Surveillance definitions are essential to public reporting and quality improvement efforts, but do not replace the need for valid and reliable definitions that can be used in prospective clinical research and in clinical practice. Tightening of the new VAP definition will result in fewer numerical cases, even if the level of the condition in clinical practice does not change.

It is important to keep in mind that this is a surveillance definition. However, given that the clinical diagnosis of VAP remains imprecise, we predict that the surveillance definition will indeed be insinuated into clinical research and practice. Because previous CDC definitions have been incorporated as outcome measures for clinical research studies, it is likely that the new definitions will be used in research as well, even though they may not have the precision necessary to evaluate clinical interventions. The ARDS and VAE definitions were developed to serve a particular purpose; appropriating them for other purposes may be difficult at best and disastrous at worst.

Additional complexity is introduced because the entities themselves, ARDS and VAP, have taken on political implications as they have become the focus of public reporting, judgments about quality of care, and pay-for-performance considerations. We have argued that an emphasis on eradicating identified cases of VAP may have unintended consequences, including a tendency to underdiagnose the condition and to empirically overtreat.<sup>6</sup> A new definition for VAP does not address these underlying issues.

## Conclusion

We applaud continuing efforts to improve the validity and precision in the definition of critical care conditions. Coming to consensus is imperative for ARDS and VAP because of their importance to outcomes in critically ill patients. What directions do these definitions provide for the future? Better detection strategies for critical elements are needed. Improved diagnostic capabilities would benefit research, clinical care, and surveillance. Identification of biomarkers associated with these conditions may help, but is unlikely to be a panacea. As knowledge advances, additional refinement in definitions will follow.

The statements and opinions contained in this editorial are solely those of the coeditors.

## FINANCIAL DISCLOSURES

None reported.

## eLetters

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