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One Guideline May Not Fit All: Tailored Evidence May Improve Critical Care Delivery

6 Katharine E. Secunda, M.D.,¹ and Joanna L. Hart, M.D., M.S.^{1,2,3}

¹Division of Pulmonary, Allergy, and Critical Care, ²Palliative and Advanced Illness Research Center, Department of Medicine, and ³Department of Medical Ethics and Health Policy, University of Pennsylvania, Philadelphia, Pennsylvania

ORCID ID: 0000-0001-5617-741X (J.L.H.).



The overall objective of critical care is to restore patients with life-threatening illnesses to health states aligned with their individual values while avoiding burdensome therapies. Burdensome therapies include treatments or interventions that are intolerable to the patient or that are unlikely to result in a health state acceptable to the patient. To achieve critical care's objectives, clinicians must integrate clinical data with diagnosisor disease-based evidence to determine an individual patient's likely diagnosis, prognosis, and expected response to specific treatments. But clinicians must also assess the value the patient places on possible resulting health states and the interventions required to achieve those outcomes (1). Clinical practice guidelines and evidencebased clinical pathways guide care for common critical care syndromes (e.g., sepsis and acute respiratory distress syndrome) (2, 3). Yet, there is widespread recognition that critically ill patients, even with the same critical illness syndrome, constitute a highly heterogeneous population (4). As such, uniform application of clinical recommendations based on diagnosis may fail

to account for variation in individual patients' likely outcomes, given their baseline health and personal values (1).

For example, clinicians must know how best to use respiratory support interventions such as noninvasive ventilation (NIV) and invasive mechanical ventilation (IMV) in acute respiratory failure due to pneumonia. IMV can be lifesaving, but it may also be more burdensome to patients and costly, and it often fails to rescue patients from death (5). NIV use in such patients may be associated with decreased need for IMV (6); yet, it may also increase complications and mortality compared with IMV alone (7). NIV can also cause significant discomfort and aspiration and is typically avoided or used cautiously in patients with compromised upper airway function or with difficulty clearing secretions (8). Without clinical guidelines supporting the practice (9), there have been dramatic increases in NIV use among patients with pneumonia, presumably as clinicians weigh these complex trade-offs (10).

Clinicians' deviation from clinical guidelines may reveal a perceived limitation of them: that these standards may be based on evidence that does not account for the heterogeneity inherent in critically ill populations or that evidence guiding therapies in certain patient groups does not exist. Thus, clinicians require additional effectiveness evidence to better understand how unique patient groups, particularly those clinically excluded or underrepresented in existing efficacy or effectiveness studies, may respond to standardized clinical pathways or treatment guidelines.

In this issue of *AnnalsATS*, Teno and colleagues (pp. 1364–1370) provide novel evidence evaluating the comparative effectiveness of NIV and IMV in persons with advanced dementia and recent nursing home stays hospitalized with pneumonia or septicemia with pneumonia (11). Patients with advanced dementia and respiratory

failure make up an increasing portion of intensive care unit (ICU) admissions (12). Despite this, there is little evidence to guide clinical decision making about the use of advanced respiratory support in this patient population. This population is known to have a high likelihood of poor outcomes after critical illness, and the acceptability of valuesensitive therapies to individual patients is often unknown. With evidence of the relative risks and benefits of NIV or IMV for such patients, clinicians may more effectively tailor critical care delivery for patients with advanced dementia experiencing acute respiratory failure.

The authors leveraged the Minimum Data Set, a federally mandated assessment required of all nursing home residents, to collect comprehensive clinical information (e.g., cognitive functioning, functional status, and clinical condition) and sociodemographic data to retrospectively identify the study cohort. The authors found that among hospitalizations between 2015 and 2017, 12.4% of patients were treated with IMV only, 7.1% received only NIV, and 1.1% received both NIV and IMV. The 1-year mortality rate in both groups receiving a form of mechanical ventilation was very high, greater than 85%. Using propensitymatching and further analysis, they found that patients who received IMV experienced a modestly lower 30-day mortality than those treated with NIV (51.9% vs. 58%). Notably, this difference was not present 1 year later. The adjusted healthcare expenditures were nearly two times higher for patients who received IMV than for those who received NIV.

This study offers important insights into how to provide advanced respiratory support for patients with advanced dementia. The authors successfully used retrospective data to generate novel effectiveness information among a patient population for whom randomized clinical trials would be cost-prohibitive, infeasible, or ethically

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challenging. There are, however, clear limitations to this approach. Even with the robust clinical information from the Minimum Data Set and Medicare claims data, there were persistent imbalances after matching. The authors were unable to match on acute severity of illness scores for the critical illness episode, which may have contributed to this imbalance. The use of propensity-matched methods only allows inclusion of measured confounders, and it is likely that residual confounding remains. Several important variables that influence decision making are unaccounted for in this analysis, such as communication practices or patterns and patients' and families' values, goals, and preferences. In addition, patient selection for IMV versus NIV likely varied systematically across individual clinicians and ICUs on the basis of available resources and institutional norms (13). Finally, we do not know how many patients had clear contraindications to NIV, nor can we be certain about when NIV use preceded IMV use (i.e., treatment failure) for the patients who received both treatments.

On the basis of their results, the authors propose that NIV may be used as a time-limited trial (TLT) in the management of acute respiratory failure in patients with advanced dementia and pneumonia. TLTs are a care delivery model that may support clinicians and surrogates in circumstances in which the most likely outcomes are uncertain or to promote high-quality decision making (14). The use of NIV in this manner may allow additional time for clinicians and surrogate decision makers to discuss the burdens and benefits of IMV and clarify patients' values and goals. However, patients with advanced dementia may have relative or absolute contraindications to NIV (e.g., poor mental status and difficulty managing secretions). In such circumstances, it may be inappropriate for clinicians to use a TLT of NIV without first clarifying patients' values. We agree with the authors that, given this patient group's health states before acute respiratory failure, discussing and documenting patients' values with regard to tolerable interventions and health states

before an acute illness episode would be more likely to result in value-aligned, patient-centered care. Further evaluation of how strategic NIV use may impact outcomes beyond mortality and costs, such as hospital-free days (15) and familycentered outcome measures (16), would inform clinical implementation of this proposed approach.

Beyond its specific clinical question, the authors' work is also an example of an important approach to critical care intervention evaluation. Our field increasingly recognizes that critical care confers both benefits and long-lasting burdens on patients, families, and clinicians. Therefore, building an evidence base that helps us tailor our care, embracing the heterogeneity of our ICU populations and recognizing that they have diverse critical care needs, is necessary to achieve our objective of providing patient-centered, value-aligned care.

<u>Author disclosures</u> are available with the text of this article at www.atsjournals.org.

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