

## COULD MULTICENTER TRIALS OPTIMIZE THE COST OF PROLONGED MECHANICAL VENTILATION?

By Peter E. Morris, MD, and Kathleen Dracup, RN, DNSc



Only a small minority of patients admitted to intensive care units (ICUs) go on to require prolonged mechanical ventilation (PMV) and hence become the population we refer to as “chronically critically ill.” Among our patient populations, these individuals require the longest ICU and hospital stays and the greatest share of our time and resources. In terms of US healthcare, they account for a disproportionate amount of bed and resource utilization on a per-patient basis. But despite the millions of ICU dollars spent, daily management options for these patients have not been rigorously studied to determine how to optimize care or reduce costs.

The chronically critically ill are an intimidating population to study because of their heterogeneity. Heterogeneity within a study population creates study design challenges to account for patient-to-patient differences. PMV patients have a multitude of heterogeneities that must be accounted for in study design. Such patients vary in terms of their premorbid illnesses and in their cause of admission. Perhaps the most subtle aspect of their heterogeneity is a result of the variation of ICU management they receive over their prolonged stay. A recent European Respiratory Society consensus statement<sup>1</sup> on weaning classified ICU patients requiring mechanical ventilation into 3 groups. Class III is the prolonged weaning

group, and the definition here is surprising: those in class III fail at least 3 weaning attempts or require more than 7 days of ventilation after the first spontaneous breathing trial. Also, they have a 25% ICU mortality rate. We have yet to address this mortality with intervention studies sufficiently large to account for the PMV population’s heterogeneities.

### Economics of the Chronically Critically Ill

Halpern et al<sup>2</sup> estimated in 2000 that hospitals’ critical care activity used 14.4% of all inpatient days and cost about one-half of 1% of the US gross domestic product. This is a powerful statistic given that all US healthcare costs account for roughly 16% of the gross domestic product.<sup>3</sup> Dasta et al<sup>4</sup> proposed that although critical care beds comprised only 10% of US hospital beds, nearly one-third of inpatient costs are attributable to care within ICUs.

Possibly only one-third of all ICU patients require mechanical ventilation, but mechanically ventilated patients are associated with a much higher percentage of ICU-related costs than are non-mechanically ventilated patients.<sup>4</sup> Some argue that ICU patients who are mechanically ventilated for at least 3 weeks consume a higher percentage of dollars spent on ICU care. These patients are increasingly visible in our ICUs; Cox et al<sup>5</sup> estimate that there are more than 100 000 new PMV patients annually in the United States alone. Although annual inpatient expenditures for

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the mechanical ventilation population have been estimated to exceed \$20 billion, extended stay facility costs (including long-term acute care, rehabilitation, and skilled nursing facilities) typically are not included. More than 80% of PMV patients are discharged to such a facility, and, despite the cost, mortality in the first year after discharge from the ICU may exceed 50%.

Given the anticipated increase in an aging population, we can expect an increase in the PMV population in our ICU units. Yet despite the volume of dollars spent on the management of PMV patients, data about how best to manage such patients are sparse.

### When Should We Initiate Interventions Targeted Toward These Populations?

It is difficult to identify PMV patients at the outset of their ICU stay. However, it is within this long-term population of patients that management practice variability might benefit from an intervention study. Many recent ICU intervention studies have targeted the intervention within the first 6 to 48 hours of patients' stays in the ICU. Multicenter trials focused on PMV patients could begin much later, when these patients have already declared themselves. No large multicenter trials currently target an intervention specifically designed to reduce practice variation among PMV patients.

Many of us suspect that wide variability exists in the day-to-day care delivered to these patients, with resulting differences in morbidity and mortality. A multicenter, randomized clinical trial design could account for patient-to-patient heterogeneity and hospital-to-hospital differences in the organization of care and its delivery. Such a design might provide answers about optimizing management techniques as well as the economic consequences of such treatments. The number of patients who can

be studied at 15 centers in a 2- to 3-year period is far greater than the number of patients who could be recruited for study from one hospital alone. Longer intervention studies conducted at a single site run the risk of ignoring the possibility that day-to-day management preferences change over time. In other words, "usual" care at the beginning of a trial may differ from care at the end of that trial, thereby biasing the outcome.

### What Questions Should We Ask?

There is a long list of care delivery options for PMV patients and therefore many potential study questions. For example, how aggressively is diuresis following shock resuscitation achieved in PMV patients? How aggressively is heart failure addressed? How early and consistently is caloric intake measured? How soon after onset of mechanical ventilation should tracheostomy be pursued—if at all—and how aggressively are post-tracheostomy management concerns addressed? Pain control, prevention and treatment of delirium, initiation and timing of palliative care, appropriate skin care, maintenance of mobility, and restoration of normal communication are but a few relevant issues, all of which are important.

Intervention studies may help to reduce the variability of our current attempts to liberate PMV patients from the ventilator and the ICU. Once patients are defined as PMV, what parameters should be used to determine when to wean them? Should strength determination in upper or lower extremities or nutritional status be taken into account prior to weaning? What is the best way to organize care for PMV patients? Should care be provided in the ICU or a step-down unit? What training is required for staff? What is the optimal patient-staff ratio?

### Future Challenges for Studying the Chronically Critically Ill

Many study design challenges await those who study the PMV population. Accurate representation of an intervention's savings and actual data collection may be 2 of the most difficult. Shortening an ICU stay saves only the cost of what is referred to as the "marginal" or later ICU days.<sup>6</sup> An ICU day cost is composed of "fixed" costs (eg, cost of heating and lighting the ICU, nursing staff salaries) and "variable" costs (eg, consumption of drugs, cost of devices and

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procedures). A “marginal” ICU day typically is not equivalent in cost to even the “average” ICU day, because initial ICU days are the most expensive with respect to variable costs; fixed costs of early or late ICU days are equivalent. Therefore, realistic demonstration of the cost “savings” for such PMV interventions must account for ICU costs appropriately. How should the economic data be focused? Which perspective is most meaningful?

The design of these trials could focus on the economics of the hospital’s cost perspective, governmental or private insurers’ perspectives, or patients’ and families’ perspectives. It is unknown to what extent families’ wages are affected when a family member requires a prolonged ICU stay, yet these wages may be an important component in the economic costs of caring for a PMV or chronically critically ill patient.

Data collection challenges will result from the many silos that exist across our healthcare system. Investigators, grant agencies, and institutional review boards must decide how to bridge the barriers that are caused by the frequent transfer of these patient populations to facilities that are not related to the primary hospital academically or from a business standpoint. Difficulties in studying these populations across primary hospitals to long-term care facilities or patients’ homes will arise. Research centers in universities have not found it easy to track patients across institutions when the institutions to which patients are sent have different affiliations from the primary hospital.

### Adjusting Our Funding Priorities

Unfortunately, the limited funds for research staff who must cross many institutions simultaneously present logistical hurdles. The willingness of institutions to accept cross-institutional research staff will be a priority. These research staff must contend with a number of different institutional review boards, different healthcare staffs, and different record systems.

Needless to say, it may be time for the critical care community to focus not only on initial ICU management strategies, but on the very difficult task of studying management strategies in PMV and chronically critically ill populations. Such trial design would initiate special therapies and strategies targeting patients after they are declared as PMV or chronically critically ill. These studies will need to account for prehospitalization comorbidities, admission injuries, and any potential injuries resulting from ICU exposure itself.

The ability of the critical care community to design such trials is not the limiting factor here; it is the willingness of government and private granting agencies to determine the value of such expensive trials and to make funding a priority that poses challenges. Given current US expenditures on the chronically critically ill, it may be time for these agencies to make such research investments.

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

### FINANCIAL DISCLOSURES

None reported.

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