Patients requiring prolonged mechanical ventilation (PMV) are rapidly increasing in number, as improved ICU care has resulted in many patients surviving acute respiratory failure only to then require prolonged mechanical ventilatory assistance during convalescence. This patient population has clearly different needs and resource consumption patterns than patients in acute ICUs, and specialized venues, management strategies, and reimbursement schemes for them are rapidly emerging. To address these issues in a comprehensive way, a conference on the epidemiology, care, and overall management of patients requiring PMV was held. The goal was to not only review existing practices but to also develop recommendations on a variety of assessment, management, and reimbursement issues associated with patients requiring PMV. Formal presentations were made on a variety of topics, and writing groups were formed to address three specific areas: epidemiology and outcomes, management and care settings, and reimbursement. Each group was charged with summarizing current data and practice along with formulation of recommendations. A working draft of the products of these three groups was then created and circulated among all participants. The document was reworked with input from all concerned until a final product with consensus recommendations on 12 specific issues was achieved. (CHEST 2005; 128:3937–3954)

Key words: assessment; Diagnosis Related Group; epidemiology; long-term acute care; patient management; prolonged mechanical ventilation; reimbursement; short-term acute care

Abbreviations: APACHE = acute physiology and chronic health evaluation; CMS = Center for Medicare and Medicaid Services; CS = cardiac surgery; DRG = Diagnosis Related Group; fVT = respiratory frequency/tidal volume; GMLOS = geometric mean length of stay; HHC = home health care; HHH = hospital-within-a-hospital; IRF = inpatient rehabilitation facility; LOS = length of stay; LTAC = long-term acute care; NIV = noninvasive mask ventilation; P0.1 = airway pressure 100 ms after an inspiratory effort against a closed shutter; Pmax = maximal inspiratory pressure; PMV = prolonged mechanical ventilation; PPS = Prospective Payment System; PS = pressure support; RUG = resource utilization group; SBT = spontaneous breathing trial; SNF = skilled nursing facility; SThAC = short-term acute care

CONFERENCE FORMAT AND GOALS

In May 2004, NAMDRC, formerly the National Association for Medical Direction of Respiratory Care, a physician advocacy organization for excellence in the delivery of respiratory and critical care (namdrc.org), sponsored a 2-day conference on “best practices” associated with the care and management of patients requiring prolonged mechanical ventilation (PMV). The goal was to review existing practices and develop recommendations on a variety of assessment, management, and reimbursement issues associated with patients requiring PMV. Conference *From Duke University Medical Center (Dr. MacIntyre), Durham, NC; Tufts New England Medical Center (Dr. Epstein), Boston, MA; University of North Carolina (Dr. Carson), Chapel Hill, NC; Barlow Respiratory Hospital (Dr. Scheinhorn), Los Angeles, CA; University of Colorado (Dr. Christopher), Denver CO; and Kindred Healthcare (Dr. Muldoon), Louisville, KY.
†A complete list of the participants is given in the Appendix.
participants included invited speakers and panelists along with representatives from the American College of Chest Physicians, the American Thoracic Society, the American College of Physicians, the American Academy of Home Care Physicians, the American Association for Respiratory Care, and the Society of Critical Care Medicine, and sponsors from industry.

On the first day of the conference, the speakers and panelists reviewed a wide range of topics. On the second day, three writing groups were formed and a chairperson for each group was appointed. The first group addressed epidemiology and outcomes, the second group addressed management and care settings, and the third group addressed reimbursement issues. Each group was charged with summarizing current data and practice along with formulation of recommendations.

A working draft of the products of these three writing groups was then created and circulated first among the writing group chairmen and later among all participants. The document was reworked with input from all concerned until a final product with consensus recommendations on 12 specific issues was achieved. The results are presented below.

**Issue 1: What Constitutes PMV?**

The definition of PMV depends on what body defines it: regulatory bodies, caregivers, or investigators publishing in this field. Defining what constitutes PMV is of considerable relevance. Analogous to staging a disease process, a uniform definition is essential for interpreting the literature, analyzing outcomes data (including benchmarking), guiding management decisions (including the site of care), and influencing reimbursement schemes. A uniform and broadly accepted definition is also essential as a starting point for prospective epidemiologic studies and for enrolling patients in randomized controlled trials.

In surveying the existing literature, PMV has been variously defined as \( > 24 \text{ h} \), \( > 2 \text{ days} \), \( > 14 \text{ days} \), or \( > 29 \text{ days} \) of mechanical ventilation or, alternatively, the need for post-ICUs mechanical ventilatory support. The most widely applied definitions involve patients who fall under several of the Center for Medicare and Medicaid Services (CMS) Diagnosis Related Groups (DRGs) focused on mechanical ventilatory support (DRG 475, respiratory disease and mechanical ventilation \( > 96 \text{ h} \); DRG 483, tracheostomy with mechanical ventilation \( > 96 \text{ h} \) with principal diagnosis except for face, head, and neck diagnoses; DRG 541, tracheostomy with mechanical ventilation \( > 96 \text{ h} \) with principal diagnosis except face, mouth, and neck diagnosis with major operating room procedure; DRG 542, tracheostomy with mechanical ventilation \( > 96 \text{ h} \) with principal diagnosis except face, mouth, and neck diagnosis without major operating room procedure. Generally, these patients who have required at least \( 6 \text{ h} \) of mechanical ventilation for \( > 21 \) consecutive days. This 21-day stipulation is consistent with the observation that the majority of patients who are transferred to a long-term acute care (LTAC) hospital receiving mechanical ventilation have received ventilation for at least 21 days.”

The CMS requirement of \( \geq 6 \text{ h/d} \) may be too stringent, as even shorter periods of mechanical ventilation through an artificial airway may have important implications for the selection of a care site and for equipment needs (e.g., a ventilator is still needed even if \( < 6 \text{ h/d} \) of ventilatory support is required). Conversely, the large number of stable outpatients who use noninvasive mask ventilation (NIV) at night suggests that the need for NIV should only connotate ventilator dependence when required for \( \geq 6 \text{ h/d} \) (or more than a nocturnal application).

**Recommendation 1**

PMV should be defined as the need for \( \geq 21 \) consecutive days of mechanical ventilation for \( \geq 6 \text{ h/d} \). Research is needed to better understand which definitions of PMV are most commonly used, how they are currently being employed, and how they impact costs, outcomes, and reimbursement in the United States.

**Issue 2: What Are the Epidemiology and Natural History of PMV?**

**Incidence/Prevalence**

The incidence and prevalence of PMV depends on the setting studied and definitions used. Prospective cohort studies are perhaps the best sources for this information, although they are often limited to specific sites that may not be readily generalized to other settings. Such studies have demonstrated that 5 to 20% of the patients supported with mechanical ventilation in the ICU will not wean in 2 to 4 days. One international prospective cohort study in 1998 of patients receiving mechanical ventilation from 361 ICUs indicated that 25% of patients received mechanical ventilation for \( > 7 \) days.

The APACHE (acute physiology and chronic health evaluation) III database may more accurately reflect the ICU population of patients receiving mechanical ventilation. This data set included patients consecutively admitted to adult medical and
surgical ICUs at 40 different institutions between 1988 and 1990. However, cardiac patients and coronary artery bypass graft patients were not represented. Twenty-six of these 40 hospitals were chosen randomly to represent variations in size, teaching status, and geographic region. In this large cohort, 20% of patients receiving mechanical ventilation on day one of ICU admission underwent mechanical ventilation for ≥ 7 days. In the smaller APACHE II database, 5.8% of all ICU patients received mechanical ventilation for ≥ 7 days. Multicenter studies using more strict definitions of PMV such as > 21 days have not been performed; however, single-center studies indicate that approximately 3 to 7% of patients receiving mechanical ventilation meet such criteria.

Population-based studies of PMV often utilize former DRG 483 to identify patients in large administrative databases. In 1998, the MEDPAR database of Medicare discharges recorded 43,708 Medicare patients discharged with DRG 483. This of course excludes most patients < 65 years old. An analysis of the National Inpatient Sample, a database containing information on all discharges from multiple hospitals in 22 states, estimated that there were 88,000 patients of all ages discharged under DRG 483 in 1997. This is consistent with the MEDPAR data, as 52% of the patients were ≥ 65 years of age (ie, would qualify for Medicare benefits) and 37.5% of patients died during hospitalization.

An analysis of data from a statewide database in New York between 1992 and 1996 noted an increase in the number of adult discharges with DRG 483 from 5,619 in 1992 to 9,351 in 1996. A similar analysis from a statewide database in North Carolina between 1993 and 2002 revealed a 78% increase in the number of patients receiving mechanical ventilation who were discharged with DRG 483 (43.2/1,000 such patients in 1993 to 77.1/1,000 in 2002). Although patients receiving mechanical ventilation were more likely to undergo tracheostomy in 2002 (7.7% in 2002 vs 4.3% in 1993), there was still a 46% increase in the number of PMV patients when taking this into account. Further analyses revealed a decrease in median age for the PMV patients (65 years in 1993 to 62 years in 2002) but an increase in the number of associated comorbidities. Acute care in-hospital mortality decreased from 44 to 25% over this time, but surviving patients were much more likely to be discharged to a skilled nursing facility (SNF) or other institution rather than to home.

Outcome

Hospital survival for adult PMV patients in the short-term acute care (STAC) hospital setting ranges from 39 to 75%, depending on the patient population and definition for PMV. Hospital survival in various non-STAC hospital settings varies from 50% in many series, to as high as 94%, depending on admission criteria and likelihood of transfer to a different facility when patients become acutely ill. These wide variations in patient populations, facility resources, and admission/discharge practices greatly limit the value of hospital survival as a meaningful outcome to follow across care settings. Long-term outcomes, such as 1-year survival, may be more meaningful from a clinical perspective and have been reported to range from 23 to 76%.

As in the general population of critically ill patients, there is great interest in being able to predict survival in patients requiring PMV. Accurate estimates of survival would help physicians and other care providers provide patients and families with realistic expectations for outcome. This could then facilitate resource planning and end-of-life planning as appropriate. Accurate survival estimates could also assist hospitals, post-acute care facilities, and payers manage resource allocation. Unfortunately, survival prediction in PMV patients has the same limitations as in the general population of critically ill patients. Equally problematic is the fact that current approaches to estimating acute ICU survival have not been shown to greatly affect decisions to provide aggressive care.

To date, survival prediction in PMV patients has only been addressed in the LTAC setting. These studies have had to use different approaches than those used in the acute care ICU because the laboratory and clinical assessments necessary each day to calculate and trend severity of illness in an acute care ICU (ie, to calculate various scores) are often not routine in many PMV care settings.

One model predicting hospital survival in LTAC patients was developed using patients admitted to four different centers of a single hospital network. Using number of organ failures and presence of infection, the model demonstrated adequate discrimination (area under the receiver operating characteristic curve of 0.81), but goodness of fit was not reported. It remains to be seen whether performance of the model can be reproduced in other hospitals in their network or in other LTAC settings.

In a cohort of 133 patients admitted to a single LTAC, age, functional status prior to acute illness, and diabetes were independent predictors of death 1 year after LTAC admission. Combining the two strongest predictors, age and prior functional status, produced a model that identified a group of patients at very high risk for death at 1 year. Patients who were ≥ 75 years old or ≥ 65 years old and had poor prior functional status had only a 5% likelihood of
being alive after 1 year. All other patients had a 56% chance of surviving a year. This model has yet to be validated in other settings.

Caution must be used when using age as predictor in these models because several studies\textsuperscript{30,31} have shown that age is not a strong risk factor for death in the general ICU population when controlling for acute physiology and comorbidities. However, recent data from one center\textsuperscript{3} including patients requiring > 2 days of mechanical ventilation have shown that while acute physiology is the primary risk factor for death within the first 14 days after ICU admission, age and comorbidities are the primary risk factors after 14 days.

Survival may not be the only outcome of interest for PMV patients. PMV patients often have a high burden of underlying comorbidities, and prolonged critical illness leaves them vulnerable to recurring episodes of acute complications with a need for subsequent hospital readmissions.\textsuperscript{32,33} PMV patients are also at risk for a high degree of suffering and permanent functional impairment.\textsuperscript{34} In one study,\textsuperscript{17} only 10% of PMV patients managed in post-ICU settings were functionally independent at 1 year. In another recent study\textsuperscript{35} of 186 PMV patients managed in an LTAC hospital, 71% survived to discharge, 23% were discharged home, and half of these (8% of the total PMV admissions) ultimately reported good functional status. Other reports\textsuperscript{36–38} have also noted that survivors often feel that their quality of life is good. However, most of these studies do not include the large number of patients who are unable to respond to quality-of-life interviews due to physical or cognitive limitations. Identifying risk factors for severe functional limitations or nursing home admission\textsuperscript{39} would be of as much value for many patients and families as predicting hospital or long-term survival.

In summary, the available studies suggest that there may be identifiable clinical and demographic factors that can identify PMV patients that are at very high risk of death or significant long-term deficits in functional status and quality of life. More studies are required, however, before any models can realistically impact decision making. The LTAC industry is accruing large databases to compliment existing databases that could be useful for these purposes. Ideally, future studies will focus on PMV patients identified in the acute hospital ICU setting as well as in LTAC hospitals. Transfer to LTAC hospitals inevitably involves some selection based on illness severity, payer status, or rehabilitation potential. Prediction models developed using consecutive patients identified in acute ICUs and followed up for 1 year would be more easily generalized to the overall PMV population.

### Recommendation 2

The number of patients meeting the definition of PMV will likely continue to increase. To better define this population, large prospective studies, especially those that begin in the acute care ICU, are needed. Predicting survival and functional outcomes are vital, but current models are not sufficiently accurate (or adequately validated) to inform decision making in individual patients.

### Issue 3. What Is the Definition of Weaning Success for the Patient Requiring PMV?

In the acute care ICU setting, weaning success is typically defined as extubation without the need for the reinstitution of ventilatory support (invasive or noninvasive) within the subsequent 48 to 72 h.\textsuperscript{40} This reflects the sentinel nature of removing the endotracheal tube and the likelihood that respiratory failure ensuing > 72 h after extubation in the acute ICU setting results from a new or unrelated process.\textsuperscript{41}

The 48- to 72-h criteria used in the acute ICU setting may not be appropriate in a PMV setting, where respiratory system recovery is slower and chronic comorbidities are prominent. Defining a time threshold for considering the tracheotomized patient with PMV successfully liberated from mechanical ventilation is thus less intuitive. Proposed definitions of weaning success in this setting include the acute ICU threshold of 48 h, 7 days, or 14 days without ventilatory support, freedom from ventilatory support at the time of hospital discharge,\textsuperscript{4,6,8,21} or at 6 months to 1 year after the onset of mechanical ventilation. Any definition of weaning success may be confounded by differences in patient population, discharge criteria, and institution specific characteristics (eg, transfers within the host hospital system). Moreover, the reinstitution of ventilatory support in a PMV patient may be required for factors that do not constitute a failure of the weaning process. Tracheostomy tube decannulation is not usually a prerequisite for defining weaning success. Although perhaps somewhat arbitrary, the importance of selecting a specific threshold for defining weaning success cannot be overstated, as it will allow assessment of the efficacy of weaning protocols, comparison between centers, and may drive reimbursement rules.

### Recommendation 3

In patients with slowly resolving respiratory insufficiency, complete liberation from mechanical ventilation (or a requirement for only nocturnal NIV) for 7 consecutive days should constitute successful
weaning. To further identify the optimal definition for weaning success, it is recommended that currently existing databases be interrogated to define the duration of liberation from the mechanical ventilator that best predicts long-term success (durability of weaning success). Prospective analysis of factors resulting in reinstitution of ventilatory support may also prove instructive in refining the definition of weaning success.

ISSUE 4. WHAT MECHANISMS UNDERLIE THE NEED FOR PMV?

Identifying the etiology for ventilator dependence is likely to be important in designing strategies to liberate patients from mechanical ventilation. It is evident that numerous factors contribute to ventilator dependence (Table 1).

Systemic Disease Factors

A preliminary report6 from a multicenter observational study in 23 LTAC hospitals encompassing > 1,400 PMV patients found an average age of 72 years and a median APACHE III acute physiologic score of 36 on admission. These patients often had coexistent nonpulmonary diseases that are associated with poor outcome. Specifically, while 43% of these patients had COPD, 54% also had cardiac disease (coronary artery disease or congestive heart failure), and 20% had neurologic disease.

Other studies of PMV patient populations have also shown a high prevalence of comorbidities that adversely affected ventilator weaning. In one study,42 of 52 patients requiring PMV and hemodialysis, none were successfully weaned and only 3 patients survived. In another investigation,43 PMV patients with severe renal dysfunction were also less likely to be successfully weaned from mechanical ventilation (13% vs 56%). Cardiac ischemia or left ventricular dysfunction can limit liberation from mechanical ventilation in the acute setting.44 Although detailed study of cardiac factors in prolonged mechanical ventilation have not been published, one preliminary report45 noted that successful diuresis and weight loss were associated with weaning success. Poor nutritional status contributes to PMV through several mechanisms: respiratory muscle dysfunction, attenuated ventilatory response to gas exchange abnormalities, and predisposition to infection. Weaning failure and PMV have also been associated with the presence of hypoalbuminemia,23,46,47 although this relationship may be as much a consequence of critical illness liver abnormalities as an effect of nutritional abnormalities.

Abnormal mental status has been linked to PMV. As an example, a study48 of patients receiving PMV, and not receiving sedative infusions, observed that patients with a modified Glasgow coma scale score of < 8 were 6.5 times more likely to have weaning failure. The emotional stress and sleep deprivation associated with acute ICU care may also contribute to abnormal mental status.

The presence of these comorbidities likely contribute to the fact that a large fraction (23 to 48%) of PMV patients outside the STAC hospital ICU require transfer back to acute care at some time.33,49–51 This STAC ICU readmission rate is likely to increase as patients admitted to PMV-focused care sites have been noted to have increasingly higher severity of illness markers (and thus more comorbidities) in recent years. Over an 8-year period, Scheinhorn and colleagues23 noted a significant trend of higher LTAC hospital admission APACHE III acute phys-

**Table 1—Mechanisms Associated With Ventilator Dependence**

<table>
<thead>
<tr>
<th>Systemic factors</th>
<th>Mechanical factors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic comorbid conditions (eg, malignancy, COPD, immunosuppression)</td>
<td>Increased work of breathing</td>
</tr>
<tr>
<td>Overall severity of illness</td>
<td>Reduced respiratory muscle capacity</td>
</tr>
<tr>
<td>Nonpulmonary organ failure</td>
<td>Critical illness polyneuropathy</td>
</tr>
<tr>
<td>Poor nutritional status</td>
<td>Steroid myopathy</td>
</tr>
<tr>
<td>Isolated phrenic nerve/diaphragmatic injury (eg, after surgery)</td>
<td>Disuse myopathy</td>
</tr>
<tr>
<td>Imbalance between increased work of breathing and respiratory muscle capacity</td>
<td>Upper airway obstruction (eg, tracheal stenosis) preventing decanulation</td>
</tr>
<tr>
<td>Iatrogenic factors</td>
<td>Failure to recognize withdrawal potential</td>
</tr>
<tr>
<td>Inappropriate ventilator settings leading to excessive loads/discomfort</td>
<td>Inappropriate ventilator settings leading to excessive loads/discomfort</td>
</tr>
<tr>
<td>Imposed work of breathing from tracheotomy tubes</td>
<td></td>
</tr>
<tr>
<td>Medical errors</td>
<td>Complications of long-term hospital care</td>
</tr>
<tr>
<td>Recurrent aspiration</td>
<td>Infection (eg, pneumonia, sepsis)</td>
</tr>
<tr>
<td>Infection (eg, pneumonia, sepsis)</td>
<td>Stress ulcers</td>
</tr>
<tr>
<td>Stress ulcers</td>
<td>Deep venous thrombosis</td>
</tr>
<tr>
<td>Deep venous thrombosis</td>
<td>Other medical problems developing in the PMV care venue</td>
</tr>
<tr>
<td>Other medical problems developing in the PMV care venue</td>
<td>Psychological factors</td>
</tr>
<tr>
<td>Sedation</td>
<td>Sleep deprivation</td>
</tr>
<tr>
<td>Delirium</td>
<td>Process of care factors</td>
</tr>
<tr>
<td>Depression</td>
<td>Absence of weaning (and sedation) protocols</td>
</tr>
<tr>
<td>Anxiety</td>
<td>Inadequate nursing staffing</td>
</tr>
<tr>
<td>Sleep deprivation</td>
<td>Insufficient physician experience</td>
</tr>
</tbody>
</table>
ioologic score and a shorter duration of preadmission mechanical ventilation. More recently, regulatory changes have lengthened LTAC preadmission time, but illness severity has continued to increase.9

**Respiratory System Mechanical Factors**

*(Load/Capacity Balance)*

As in the acute care setting, an imbalance between excess patient breathing loads and diminished respiratory muscle capacity has been identified in many patients requiring PMV.52–55 Clinical indexes of excessive loading and/or impaired capacity include lower maximal inspiratory pressures (Pmax), and high respiratory frequency/tidal volume (f/Vt) ratios during spontaneous breathing. An increased respiratory drive as manifest by high breathing frequencies or the airway pressure 100 ms after an inspiratory effort against a closed shutter (P0.1) may also indicate a load/capacity imbalance. Note, however, that the P0.1 has also been used as an index of ventilatory muscle strength.

One study56 in patients with COPD receiving mechanical ventilation for > 21 days found lower f/Vt ratios and higher P0.1 values were associated with weaning success. Another study55 evaluated 39 PMV patients (intubated for > 3 weeks), 28 with COPD and 11 who had undergone cardiac surgery (CS) complicated by diaphragmatic dysfunction. Compared to a nonventilator dependent COPD control group, the ventilator-dependent COPD group demonstrated reduced tidal volume, minute ventilation, maximal transdiaphragmatic pressure, and Pmax, while showing increased respiratory frequency, P0.1, significant intrinsic positive end-expiratory pressure, and elevated airway resistance. Compared to a nonventilator-dependent CS patient control group, ventilator-dependent CS patients had reduced tidal volume and Pmax while demonstrating higher respiratory frequency and P0.1 values. Similar to investigations in the acute setting, the majority of these PMV patients had ventilatory muscle tension time indexes values > 0.15 reflecting a high load-to-muscle-capacity ratio.55

Specific abnormalities in respiratory muscle function appear common in patients requiring PMV and having difficulty weaning.53,55,57–59 As an example, one study49 found that 62% of patients with weaning failure had electromyographic evidence of new neuromuscular disease (chronic illness polyneuropathy or myopathy). Another study51 found 96% of patients receiving ventilation for ≥ 7 days had either electromyographic or muscle biopsy evidence of neurogenic abnormalities or myopathic changes. Not surprisingly, the presence of these abnormalities correlates with longer duration of mechanical ventilation.62 In one study,63 patients requiring a period of paralysis in the ICU took twice as long to be subsequently weaned from mechanical ventilation. The role of respiratory muscle dysfunction is further suggested by investigations demonstrating improvement over time in Pmax when comparing patients failing weaning and then later at the time of weaning success.57–59

Trigger asynchrony (the inability of a patient’s effort to trigger the ventilator because of either weak muscles or inspiratory loading from intrinsic positive end-expiratory pressure) can be an important manifestation of additional load/capacity imbalances in PMV weaning difficulties. In one LTAC study,64 patients with and without trigger asynchrony were compared. In the 19 trigger asynchrony patients, only 3 patients (16%) were successfully weaned after 70 to 108 days, compared to 181 patients without trigger asynchrony, who were successfully weaned 56% of the time after a median 33 days. From a simple monitoring perspective, failure to appreciate trigger asynchrony may lead to an underestimation of the respiratory rate and therefore the f/Vt ratio.53

**Iatrogenic Factors**

A number of iatrogenic factors have been associated with PMV. First among these is the failure to appreciate ventilator liberation capabilities by not using appropriately frequent assessments or using inappropriately slow reductions in support strategies.40,65 Inappropriate ventilator settings can also slow the withdrawal process through imposed muscle loading or patient-ventilator dyssynchrony.66,67 A corollary to this is the use of unnecessary sedation either because of the dyssynchrony or because of inappropriate monitoring of actual sedation needs.68,69 As noted above, stresses related to being in an ICU along with sleep deprivation may result in mental status changes that also prompt excessive sedation use.

Abnormalities of the upper airway resulting from complications of the artificial airway can also contribute to ventilator dependence. Ten percent of patients with PMV had tracheal injury despite the use of artificial airways with low-pressure, high-volume cuffs. Indeed, in one study70 37 of 756 patients (5%) receiving PMV had evidence of distal tracheal obstruction contributing to ventilator dependence.

Tracheostomies also promote swallowing dysfunction and aspiration in PMV patients. Depending on the method of detection, 30 to 83% of patients receiving PMV have swallowing dysfunction (often silent aspiration), a factor that may contribute to failure to liberate from mechanical ventilation.71–74
Process of Care Issues

Increasing duration of mechanical ventilation has been associated with increasing risk of complications, including nosocomial infection, in the acute ICU setting. In a preliminary report from a prospective, multicenter, observational study of patients requiring PMV, infection appeared common (ie, there was evidence for treatment of urinary tract infection in 32%, lower respiratory tract infection in 28%, Clostridium difficile infection in 18%, and central line infection in 12%). Importantly, length of stay and time to wean were significantly longer for patients with apparent infection.

The capability to successfully liberate patients from mechanical ventilation is directly linked to the caregiver’s skills with patients requiring PMV. Indeed, some investigators report increasing rates of weaning success over time as caregivers acquired experience in managing patients with prolonged mechanical ventilation. Absence of an organized strategy for weaning (eg, weaning protocol) may also increase the number of patients requiring mechanical ventilation. As an example, patients weaned by protocol were less likely to require >21 days of mechanical ventilation when compared to patients weaned by a traditional approach. Additionally, it has been demonstrated that decreases in effective nursing force can lead to dramatic increases in the duration of mechanical ventilation (from 7 to 38 days).

Predicting Weaning Success Based on Dependency Factors

Clinical studies evaluating weaning predictors in the PMV population are far fewer than in the acute ICU setting. As noted above, a number of respiratory system assessments are associated with weaning outcomes. However, as also noted above, the etiology of ventilator dependence is often multifactorial in the PMV population. Thus, an approach that combines not only respiratory factors but also nonrespiratory factors into sophisticated scoring systems may prove superior in predicting weaning outcome for patients receiving PMV. Although several such approaches have been published, none of these multidimensional strategies to predicting weaning success have been independently validated.

Recommendation 4

Although numerous factors contributing to ventilator dependence have been identified, their relative frequency among cohorts of PMV patients has not been defined. Greatest emphasis should be placed on identifying factors that are potentially reversible, especially iatrogenic factors.

Issue 5. What Are the Care Venues Available for Patients With PMV?

Patients generally have mechanical ventilation initiated in the ICUs of a STAC hospital. Patients with underlying chronic cardiorespiratory diseases and/or slowly resolving acute cardiorespiratory illness remain ventilator dependent and transition from being acutely critically ill to “chronically critically ill,” or having “sustained severe illness.” With this transition, alternatives to the ICU care venue should be considered for several reasons. First, ICU beds are often in short supply, and it is generally conceded that these beds should be made available to the acutely ill needing this very high level of care. Perhaps more importantly, however, a more comprehensive patient-focused process of care than that found in an ICU (ie, a more rehabilitative than life-support focus) would be more appropriate for PMV patients. Indeed, comparing ICU care to a PMV-focused care venue (Table 2) yields prima facie evidence that the PMV patient might derive significant benefit from transfer out of the high technology environment of the ICU.

Venues providing PMV are of several types (Table 3), each with their own advantages, disadvantages and, as discussed below under “Issue 10,” reimbursement schemes. Within STAC hospitals, “step down,” “transitional care,” or “weaning” units may exist. LTAC hospitals also serve this role as either freestanding facilities or independently owned and operated “hospital-within-a-hospital” (HiH) facilities focused on the care of the chronically critically ill. These units/facilities are characterized by long length of stay, are conducive to slow-paced weaning, and caregiver staffing at the acute-care level, which may provide increased patient safety during the instability inherent in the weaning process. A recent analysis by the Medicare Payment Advisory Commission indicates overall cost of care for PMV patients are lower when part of the care is provided at an LTAC. For patients with few or stable comorbidities and stable respiratory support needs, some SNFs may offer mechanical ventilatory support capabilities. Finally, in patients with strong social support and appropriate home care support, PMV can be managed in the home environment.

Recommendation 5

Consider the environment of care from the patients’ perspective, when continuing weaning efforts in those difficult to wean from mechanical ventilation in the ICU. Venue selection should also be guided by the services each patient requires. The comorbidities that often accompany the need for PMV may preclude transfer to facilities without some level of ICU or acute care capabilities. All facilities that are available to
patients should be screened by the critical care team for effectiveness and safety when effecting discharge for post-ICU weaning.

**Issue 6. At What Point Should Patients Be Considered for Transfer From an ICU to a PMV-Focused Venue?**

As noted above, predictors of ICU PMV exist, but the individual patient’s course is usually unpredictable. The transfer from an acute ICU to a PMV-focused venue is thus usually driven by clinical assessments showing that there is a need for PMV but also a measure of clinical stability, and thus a reduced need for acute ICU care (i.e., no need for pressors or inotropes, and evidence that the acute illness has stabilized or begun to reverse). From the respiratory system perspective, this is often about the same time that a tracheostomy is performed.

Many ICUs and intensive care practitioners use informal or formal policy and procedure for timing of tracheostomy consistent with current guidelines. This is usually considered as early as day 7 when it becomes likely to the care team that PMV will be required and is often actually performed at 16 to 20 days of mechanical ventilation. Indeed, when tracheostomy is first considered, the timing is often right to begin plans for post-ICU care, as it may take 1 to 2 weeks to set up transfer to a unit or facility dedicated to this population, with the resources and expertise to give continuing care.

**Recommendation 6**

Begin considerations for PMV-focused care when tracheostomy is first considered.

<table>
<thead>
<tr>
<th>Venue</th>
<th>Patient Type</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>STAC ICU</td>
<td>All</td>
<td>Full ICU capabilities</td>
<td>Costs, life support rather than patient focused</td>
</tr>
<tr>
<td>STAC step-down</td>
<td>All except very acute</td>
<td>Most ICU capabilities at lower costs, full acute care capabilities</td>
<td>Not full ICU</td>
</tr>
<tr>
<td>LTAC</td>
<td>All except very acute</td>
<td>Most ICU capabilities at lower costs, most acute care capabilities, more patient focused</td>
<td>Not full ICU</td>
</tr>
<tr>
<td>Rehabilitation hospital</td>
<td>Stable</td>
<td>Lower cost, patient focused, occupational therapy/physical therapy focus</td>
<td>No ICU care, limited acute care</td>
</tr>
<tr>
<td>Subacute hospital</td>
<td>Stable</td>
<td>Lower cost, patient focused</td>
<td>Limited or no weaning, no ICU care, limited acute care</td>
</tr>
<tr>
<td>SNF</td>
<td>Stable</td>
<td>Lowest cost, patient focused</td>
<td>Limited or no weaning, no ICU care, no acute care</td>
</tr>
<tr>
<td>Home</td>
<td>Stable</td>
<td>Very patient focused</td>
<td>No weaning, no ICU care, no acute care</td>
</tr>
</tbody>
</table>
ISSUE 7. WHAT ARE THE SIMILARITIES AND DIFFERENCES IN VENTILATOR WEANING AND DISCONTINUATION STRATEGIES BETWEEN THE STAC ICU AND PMV-FOCUSED VENUES?

The strength of the available evidence for approaches to weaning in the PMV-focused care venue is limited to nonrandomized studies, historical control observational studies, and expert consensus. In general, the PMV population recovery is usually much slower than in most acute ICU patients, and thus what works for weaning patients in a STAC ICU (eg, daily spontaneous breathing trials [SBTs]) may not be applicable in the PMV venue. A commonly reported practice in PMV-focused venues is to wean the level of support to approximately half that required for full support (eg, pressure support [PS] levels of 10 to 15 cm H₂O) before beginning daily SBTs (Table 4). As in the ICU, assessing tolerance of support reduction involves an integrated assessment of the respiratory pattern, gas exchange (ie, from pulse oximeters), hemodynamics (ie, from heart rate/BP monitors), and patient comfort.

It is important to note that the SBT techniques used in these PMV patient studies differ from SBT techniques in the ICU setting in two ways: (1) the PMV SBT is almost always done as an unsupported “trach collar” or “T-piece” approach, as opposed to the CPAP or low level PS approach often used in the ICU; (2) the PMV SBT often involves progressive increases in duration beyond the 120-min limit often used in the ICU. Like the ICU setting, however, these SBT approaches can be successfully codified into protocols and preliminary data from a 23-site, multicenter study of weaning from PMV found 70% of the participating hospitals utilized nonphysician-directed protocol weaning. Scheinhorn and colleagues use the f/Vt ratio to accelerate ventilatory support reduction (weaning) progress through a therapist-implement protocol. They have found that weaning success was nearly twice as likely when the f/Vt was < 80 breaths/min/L, compared to > 120 breaths/min/L, and thus used this threshold of 80 breaths/min/L to allow patients to “bypass” stepwise ventilator setting reductions and successfully go straight to SBTs from even high levels of initial support. A subsequent study suggested that this threshold could safely be raised to 100 breaths/min/L.

Managing patients with PMV involves more than ventilator weaning and has a far more comprehensive “rehabilitative” focus than acute ICU care. The components of this rehabilitative model with its multidisciplinary team approach, frequency of reevaluations, protocol use, and in-depth use of adjunctive and consultative services are outlined in Table 5. While not all of the modalities contribute directly to weaning outcome, they serve global needs of this population.

Conceptually, the PMV patient management process is the opposite of that in the acute care ICU. Instead of the addition of life support or organ-system support measures to sustain life in the face of imminent loss, the patient enters the PMV-focused venue with these already in place. The “peeling off” of these support modalities, as the layers are peeled off an onion, is the best analogy to characterize successful PMV patient management. Specific implementation of the rehabilitative approach will differ between institutions, depending on resources available.

Recommendation 7

As in the acute ICU setting, individual weaning predictors in the PMV setting lack precision to guide weaning decisions. PMV weaning strategies should thus incorporate nonphysician-implemented weaning protocols that utilize daily SBTs of progressively increasing duration after a certain level of ventilatory support reduction has occurred. As many elements of the rehabilitative model as can be marshaled should be part of the overall PMV patient treatment plan.

ISSUE 8. IN A PMV-FOCUSED CARE SETTING, WHEN SHOULD ATTEMPTS AT VENTILATOR WEANING BE CONSIDERED FUTILE AND PLANS MADE FOR LIFELONG CONTINUED VENTILATORY SUPPORT OR WITHDRAWAL?

There is no body of evidence to support a set time limit for considering mechanical ventilatory support

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**Table 4—Post-ICU Weaning Strategy**

<table>
<thead>
<tr>
<th>Source</th>
<th>Decrease Support</th>
<th>SBT Technique</th>
<th>Alternative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gracey et al²³</td>
<td>IMV/PSV</td>
<td>TTO</td>
<td></td>
</tr>
<tr>
<td>Petrak†</td>
<td>ACV</td>
<td>TC</td>
<td>PSV to SBT</td>
</tr>
<tr>
<td>Bagley†</td>
<td>T-piece</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Clark and Theiss⁹⁵</td>
<td>PSV</td>
<td>T-piece</td>
<td></td>
</tr>
<tr>
<td>Latriano†</td>
<td>SIMV/PSV</td>
<td>T-piece</td>
<td></td>
</tr>
<tr>
<td>Scheinhorn⁹⁴</td>
<td>SIMV/PSV</td>
<td>TTO</td>
<td></td>
</tr>
<tr>
<td>Schenolfe⁹⁶</td>
<td>ACV</td>
<td>T-piece</td>
<td>T-piece plus NIV</td>
</tr>
<tr>
<td>O’Bryan et al⁹⁵</td>
<td>SIMV/PSV</td>
<td>CPAP</td>
<td>Flow-by</td>
</tr>
<tr>
<td>Dediuia et al⁹⁰</td>
<td>SIMV/PSV</td>
<td>TC</td>
<td></td>
</tr>
<tr>
<td>Christopher⁹⁷</td>
<td>PSV</td>
<td>TTAV</td>
<td></td>
</tr>
</tbody>
</table>

*ACV = assist-control ventilation; IMV = intermittent mandatory ventilation; SIMV = synchronized intermittent mandatory ventilation; CPAP = continuous positive airway pressure; TC = tracheotomy collar; TTAV = transtracheal augmented ventilation; TTO = transtracheal oxygen.
†Personal communications: RM Petrak, 1998; PH Bagley, 1997; B Latriano, 1996.
Table 5—Components of Rehabilitative Model of Post-ICU Weaning*

<table>
<thead>
<tr>
<th>Component</th>
<th>Responsibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>Physician services</td>
<td>Physician experienced in ventilator care/weaning</td>
</tr>
<tr>
<td></td>
<td>Hospitalist vs practitioner model</td>
</tr>
<tr>
<td></td>
<td>Leader of multidisciplinary team that meets weekly</td>
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<tr>
<td></td>
<td>Assess patient daily</td>
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<tr>
<td></td>
<td>Order plan of treatment (best practice model, standard order sets)</td>
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<tr>
<td></td>
<td>Approve, order, and monitor nonphysician-care protocols</td>
</tr>
<tr>
<td>Clinical case manager</td>
<td>Experienced nurse in PMV setting</td>
</tr>
<tr>
<td></td>
<td>Lead multidisciplinary conferences</td>
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<tr>
<td></td>
<td>Ensure communication between team members and resolve disputes</td>
</tr>
<tr>
<td></td>
<td>Ensure that care plan is carried out</td>
</tr>
<tr>
<td></td>
<td>Ensure policy and procedure uniformity</td>
</tr>
<tr>
<td></td>
<td>Monitor protocol compliance</td>
</tr>
<tr>
<td>Nutrition support</td>
<td>Registered dietitian</td>
</tr>
<tr>
<td></td>
<td>Initial and follow-up evaluations</td>
</tr>
<tr>
<td></td>
<td>Goal setting, (eg, transition from parenteral to enteral nutrition, enteral and oral feeding, optimize energy and protein delivery, tailored to volume sensitivity and organ dysfunction (eg, congestive heart failure, renal, hepatic disease, diabetes mellitus, fluid and electrolyte balance).</td>
</tr>
<tr>
<td></td>
<td>Prompt laboratory testing as appropriate</td>
</tr>
<tr>
<td>Bedside nursing</td>
<td>Registered nurse, licensed practical nurse with experience with ventilator patients</td>
</tr>
<tr>
<td></td>
<td>Cross-training with respiratory care practitioners (eg, suctioning techniques, mechanical ventilator awareness)</td>
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<tr>
<td></td>
<td>Training in patient and family education</td>
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<tr>
<td></td>
<td>Adherence to policies and procedures</td>
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<tr>
<td></td>
<td>Meticulous nursing care with focus on protocols involving tracheostomy care, indwelling lines, feeding tubes, and bladder catheters</td>
</tr>
<tr>
<td></td>
<td>Good communication with other team members</td>
</tr>
<tr>
<td>Respiratory therapy</td>
<td>Certified and registered therapists</td>
</tr>
<tr>
<td></td>
<td>Competence in use of all equipment/procedures (eg, suctioning, aerosol therapy, invasive and noninvasive mechanical ventilation, airway care)</td>
</tr>
<tr>
<td></td>
<td>Patient assessment: judgment of dyspnea, comfort, anxiety</td>
</tr>
<tr>
<td></td>
<td>Management of weaning per protocol as indicated</td>
</tr>
<tr>
<td></td>
<td>Communication to patient and care team</td>
</tr>
<tr>
<td>Pharmacy support</td>
<td>Registered pharmacists with experience in geriatric dosing</td>
</tr>
<tr>
<td></td>
<td>Review medication profiles and minimize overuse</td>
</tr>
<tr>
<td></td>
<td>Focus on minimizing sedatives</td>
</tr>
<tr>
<td></td>
<td>Involvement in patient, family, staff education</td>
</tr>
<tr>
<td>Rehabilitation services</td>
<td>Physical therapist</td>
</tr>
<tr>
<td></td>
<td>Extremity training</td>
</tr>
<tr>
<td></td>
<td>Ambulation, all muscle group training</td>
</tr>
<tr>
<td></td>
<td>Respiratory muscle training</td>
</tr>
<tr>
<td></td>
<td>Occupational therapist</td>
</tr>
<tr>
<td></td>
<td>Activities of daily living</td>
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<tr>
<td></td>
<td>Speech therapist</td>
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<tr>
<td></td>
<td>Swallowing evaluation and therapy</td>
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<td></td>
<td>Early teaching using communication tools</td>
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<tr>
<td>Psychological services</td>
<td>Professionals (psychologists/psychiatrists)</td>
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<tr>
<td></td>
<td>Patient and family evaluation</td>
</tr>
<tr>
<td></td>
<td>Anxiety vs delirium</td>
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<tr>
<td></td>
<td>Counseling</td>
</tr>
<tr>
<td></td>
<td>Aspects of geriatric and palliative care</td>
</tr>
<tr>
<td>Social services</td>
<td>Experienced social workers with access to pastoral care</td>
</tr>
<tr>
<td></td>
<td>Patient and family education and counseling in hospital</td>
</tr>
<tr>
<td></td>
<td>Problem solving</td>
</tr>
<tr>
<td></td>
<td>Palliative care aspects of treatment</td>
</tr>
<tr>
<td></td>
<td>Discharge planning (include all above disciplines, and participate early)</td>
</tr>
<tr>
<td></td>
<td>Liaison with:</td>
</tr>
<tr>
<td></td>
<td>Durable medical equipment vendors</td>
</tr>
<tr>
<td></td>
<td>HHIC services (Visiting Nurse Association)</td>
</tr>
<tr>
<td></td>
<td>Local community hospital</td>
</tr>
<tr>
<td></td>
<td>Ambulance companies</td>
</tr>
<tr>
<td></td>
<td>Power company</td>
</tr>
</tbody>
</table>

*Modified from Criner et al,84 O’Bryan et al,85 and Scheinhorn et al.94
weaning to be futile, nor when weaning attempts should cease. In the evidence-based weaning guidelines endorsed by several authoritative bodies, a time of 3 months of mechanical ventilation was extrapolated post hoc from observational studies as being a period when most patients who could be weaned had been weaned.

Relying on a strict timeline to define futility is clearly inappropriate, as many factors enter into the decision to abandon further weaning attempts. On admission to a PMV-focused care venue, the interdisciplinary team should immediately partner with the patient and family on goal setting and discharge planning. The decision to subsequently consider further weaning futile can then be made based on the following principles: (1) treatable conditions that impede weaning have been reversed/improved as much as possible; and (2) documented repeated failure to progress through a weaning protocol, even to reach modified goals (eg, nocturnal ventilation, invasive or noninvasive). An additional consideration would include a realization that resultant functionality and quality of life from the patient’s standpoint will be unacceptable, even if weaned. Finally, there might also be concern that the cardiorespiratory status might be so tenuous with complete liberation from the ventilator that transfer to a care venue with less staffing or monitoring might place the patient at an unacceptable risk.

The objective data that drive the decision to consider further weaning attempts futile should be communicated to the patient and family. In these discussions, it is important to emphasize that further weaning attempts under these circumstances are not only futile but also may cause unnecessary frustration, anxiety, and discomfort. However, the decision to cease weaning attempts should not be made until consensus on these issues is attained among the care team, the patient, and the family. If such a consensus is proving difficult to reach, palliative care services, social services, and pastoral services may be useful consultants.

Once consensus is reached that further weaning attempts are futile, the focus of discussions change. Although plans for permanent ventilatory support may be appropriate in some of these patients, many others may not wish to continue to live under these conditions, especially if significant comorbidities (especially neurologic) are present. Discussions with patients and families must be frank and open with realistic options presented. These can include continuation of ventilatory support with escalations in support as needed, continuation of ventilatory support but with a limit on escalations of care, or withdrawal of support. Each of these selections engenders the need for a careful discharge plan with clear directions for the scope of continued care. Palliative care services, social services, and pastoral services can also be helpful in these discussions. Emphasis should be placed on the fact that the underlying disease is responsible for the worsening outlook and that death is anticipated from this, not from reductions or withholding of care.

Unfortunately, these principles of communication and consensus building have been difficult to put into practice, especially in the STAC ICU setting. The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment investigators found that of 1,494 patients who spent >14 days in the ICU, <40% reported that their physicians had talked with them about their prognosis or preferences for life-sustaining treatment. Among the patients who preferred a palliative approach to care, only 29% thought that their care was consistent with that aim. The PMV-focused venues offer opportunity to improve on these important aspects of care.

 Recommendation 8

Weaning efforts should continue in the post-ICU setting until both the interdisciplinary team and the informed patient/family agree that these efforts should cease. In patients deemed unweanable, frank and open discussions with patients and families about prognosis and realistic long-term options are essential.

Issue 9. What Is the Role of Palliative Care in Patients in a PMV-Focused Venue?

Palliative care is care focused on the relief of pain, dyspnea, anxiety, and other symptoms that accompany chronic critical illness. While often associated with end-of-life care, palliative care also has a role in the treatment of all patients requiring PMV. It has been demonstrated in preliminary reports both in STAC ICU weaning and PMV weaning, that dyspnea and anxiety are common accompaniments of weaning from mechanical ventilation. In addition, most PMV patients report significant discomforts such as pain and thirst. With the addition of sleep disturbance, depression, and inability to communicate, it is clear that there are numerous symptoms that may benefit from palliative care interventions as part of the treatment of patients, and education of their families.

It should be noted that the PMV population is often elderly, has many comorbidities and complications accompanying respiratory failure, and may be near the end of the natural history of numerous conditions, eg, COPD. They, and also their loved ones, will often require counseling and education to
better understand and prepare for what lies in store for them. The multidisciplinary team can work with a consultative palliative care service, which should be employed early in the hospitalization to best assess, and then address these concerns.

Recommendation 9

A palliative care service can add value to the patient and family experience surrounding PMV care, and should be established, resources permitting.

**Issue 10. What Are the Various Payment Models Available for PMV-Focused Venues, and What Discrepancies Between Reimbursement Regulation and Appropriate Clinical Care May Be Present?**

Payment for PMV, or any medical condition, is determined by a method selected by the payer. Medicare embraced the concept of a prospective payment approach in 1983 and over the next 20 years rolled out the Prospective Payment System (PPS) to STAC hospitals, SNFs, inpatient rehabilitation facility (IRFs), LTAC hospitals, and psychiatric hospitals. Only oncology, obstetrics/gynecology, and pediatric hospitals have not been placed under PPS, the latter two largely because they have limited penetration into the Medicare population. Through the MedPAR data file, Medicare provides the largest source of data describing PMV volume and costs, and therefore any discussion of a PPS for PMV will by necessity focus on the Medicare population. PMV patients whose payer source is workers compensation, Medicaid, or private insurance are covered by plans that are individualized and therefore highly variable. The self-pay population, with the exception of the very wealthy, is generally uncompensated.

The policy behind PPS is that patients are classified at discharge into one of > 500 DRGs, each of which has a predetermined payment. CMS sets the payment annually based on an analysis of hospital costs reports, DRG volume, legislative requirements, and other budgetary considerations. The payment for each DRG is determined by multiplying the average payment for the provider type (the base rate) by the relative resource consumption of that DRG (the DRG weight) [Table 6]. DRGs associated with PMV are relatively few and include DRGs 475, 483, 541, and 542. Note that the DRGs related to performing a tracheostomy (483 and now 541 and 542) are rarely used in an LTAC setting because almost all PMV patients have the tracheostomy procedure performed at the STAC hospital.

Prospective payment as a “one diagnosis, one payment” construct is somewhat of a misnomer. Minor variations include additional reimbursement for hospitals with commitments to medical education (the indirect medical education adjustment), to those with the highest proportion of uncompensated care (the disproportionate share adjustment), geographic adjustments for capital costs, and adjustments in reimbursement to reflect geographic differences in labor costs (the wage rate index adjustment). The PPS also includes an outlier policy with payments to take into consideration patients who are clearly were much more costly than the average patient envisioned by the DRG reimbursement. The outlier policies for STAC and LTAC hospitals are different and described in more detail in sections below.

The principal advantage of PPS is its conceptual

<table>
<thead>
<tr>
<th>DRG</th>
<th>Description</th>
<th>STAC Payments†</th>
<th>STAC GMLOS</th>
<th>LTAC Payments†</th>
<th>LTAC GMLOS</th>
</tr>
</thead>
<tbody>
<tr>
<td>475</td>
<td>Respiratory system diagnosis with ventilatory support</td>
<td>$17,981</td>
<td>8.0</td>
<td>$77,405</td>
<td>34.2</td>
</tr>
<tr>
<td>483*</td>
<td>Tracheostomy with mechanical ventilation ≥ 96 h with principal diagnosis except for face, head, and neck diagnoses (2004 weight)</td>
<td>$83,411</td>
<td>34.2</td>
<td>$118,348</td>
<td>55.7</td>
</tr>
<tr>
<td>541*</td>
<td>Tracheostomy with mechanical ventilation ≥ 96 h with principal diagnosis except face, mouth, and neck diagnosis with major operating room procedure</td>
<td>$99,646</td>
<td>38.7</td>
<td>$129,593</td>
<td>56</td>
</tr>
<tr>
<td>542*</td>
<td>Tracheostomy with mechanical ventilation ≥ 96 h with principal diagnosis except face, mouth, and neck diagnosis without major operating room procedure</td>
<td>$59,806</td>
<td>27.5</td>
<td>$108,057</td>
<td>45.9</td>
</tr>
</tbody>
</table>

*As of October 2004, the CMS has replaced DRG 483 with DRGs 541 and 542.
†Payments are determined by multiplying the base rates (for 2005, the base rates for STAC and LTAC are $4,972 and $36,833, respectively) by DRG weights. Weights for STAC and LTAC are as follows: DRG 475, 3.6166 and 2.1015; DRG 483, 16.7762 and 3.2131; DRG 541, 20.0414 and 3.5184; and DRG 542, 12.0286 and 2.9337, respectively.
simplicity: pay all hospitals the same for similar patients, and let the law of averages balance out patient difference. With PPS, hospitals know how much they will be paid, payers (e.g., Medicare) can predict payments and prepare projections relatively easily, and policy makers can adjust the payment for all patients simply by changing the base rate and/or DRG weights. In keeping with policy goals, providers continually have the incentive to reduce the cost of care. The disadvantages of PPS reflect its crudeness, including an unpredictable margin profitability for low-volume providers, a financial disincentive for providers to treat high-cost cases, and the lack of relationship between the payment and individual patient’s clinical needs within a DRG (lack of risk adjustment). At present, while CMS recognizes the benefit of “paying for quality,” it appears so committed to PPS that any realistically proposed payment system must work within the confines of a prospective, per-case payment system.

STAC Hospitals

STAC hospitals have been under a PPS since 1983. While initially financially painful, adjustments in medical and hospital practices and the development of community resources that permitted earlier discharge and a shorter length of stay (LOS) have made PPS workable for most STAC hospitals. Hospitals that could not adapt either closed or were consolidated into systems with leaner cost structures or more favorable patient populations.

In the STAC DRG system, when costs exceed the DRG reimbursement, the provider must absorb a nonreimbursed “fixed-loss outlier threshold” of approximately $25,800, after which Medicare will reimburse the provider 80% of a formula-derived “cost.” In keeping with the cost-control premise for PPS, it is the intent of the outlier policy that outlier care always will be a financial loss to the hospital (i.e., hospitals will not profit from outlier payments).

LTAC Hospitals

With a few exceptions, the LTAC DRG system uses the same DRGs as the STAC hospital, although with a different reimbursement weight for each DRG (Table 6). The LTAC outlier policy has a lower fixed-loss outlier threshold of approximately $17,800 for 2005, and also reimburses 80% of subsequent costs. Approximately 8% of the CMS LTAC budget is allocated for high cost outliers, with 6% being used in 2004. In theory, these high-cost outlier losses will be partially compensated for by patients who are treated for less than the DRG payment (the law of averages), with the high-cost outlier payments acting as a “stop-loss” coverage. However, unlike the STAC PPS, in the LTAC PPS there is a financial penalty for treating patients “too quickly.” Patients who are discharged with an LOS < 5/6 of the historical geometric mean LOS (GLOS) for that DRG receive a payment that is almost always lower than the DRG payment. Short-stay outlier patients can be as many as 30 to 40% of all LTAC patients. While this removes some of the compensatory “upside” from below-average-cost patients designed to subsidize the “downside” above average-cost patients, the policy intent is to prevent LTAC hospitals from providing STAC at the higher LTAC reimbursement levels.

The LTAC PPS also regulates payment for patients who are discharged but readmitted to the LTAC. Under this “interrupted stay” policy, patients discharged from the LTAC to home, STAC, SNF, or IRF and who are subsequently readmitted to the same LTAC prior to a threshold number of days will not receive an additional LTAC DRG payment. The intent of this policy is to prevent discharge prior to the patient’s clinical readiness and to prevent patients from transferring between provider sites for the purpose of receiving additional reimbursement. The interrupted stay thresholds for discharges to home, STAC, IRF, and SNF are 3, 9, 27, and 45 days, respectively. Therefore, all patients admitted to LTAC must be screened to determine if they had an LTAC admission within those thresholds.

There has been substantial growth in the number of LTAC facilities and in LTAC spending over the past decade. In 1993, there were 105 LTAC hospitals, compared to approximately 330 in 2005; LTAC cost to Medicare increased from $398 million in 1993 to $3.1 billion in 2004. In an effort to understand this growth in spending, LTAC reimbursement rules have been recently scrutinized by the CMS. A specific CMS concern has been related to the relationships of HiH LTACs and the host STAC hospital. The CMS is specifically concerned about potential incentives to transfer patients based on reimbursement potential rather than patient care needs. In response to this perception, in October 2004, the CMS passed regulations informally known as the “25% rule.” Subject to a transition period, these rules essentially limit the number of patients that an HiH LTAC may receive from the host hospital to 25% of its total census. It further expands the practical definition of an HiH to any LTAC hospital located within 250 yards of a STAC hospital. While the intent is to reduce the interdependency of the STAC and LTAC hospital pair, the rule will also limit the access of some STAC patients to LTAC hospitals that are geographically convenient to them and/or their physicians and could thus hamper the provision of appropriate levels of care for PMV patients in the future.
STAC-LTAC Transfer Policy

In order to prevent providers from receiving an excessive reimbursement when the patient is transferred between providers, Medicare has developed a “transfer policy.” When a patient is transferred between different provider within the same category (between STACs or between an STAC and an LTAC) prior to the GMLOS for the DRG assigned by the transferring hospital, the transferring hospital receives a reduced DRG payment. Independent DRG payments are given to both providers for patients who are transferred after this GMLOS threshold.

CMS has identified 30 “transfer DRGs” that fall under the transfer policy, excluding DRG 475 but including old DRG 483 and the newly adopted tracheostomy-related LTAC DRGs 541 and 542. Under this system, the transferring hospital receives a fraction of the total DRG reimbursement prorated based on the fraction of days of care provided at the transferring hospital. This provides a financial disincentive for the transferring hospital to make an “early” discharge to another acute care hospital, either STAC or LTAC. A receiving LTAC hospital receives a regular payment regardless of how the transfer policy pays the referring STAC hospital.

SNFs

Approximately 20% of SNF patients fall under Medicare coverage. In contrast to the per-case DRG reimbursement of STAC and LTAC hospitals, SNFs are reimbursed on a per-diem basis based on the intensity of restorative and rehabilitative services provided, and grouped into categories of similar patients. These resource utilization groups (RUGs) are established on admission to the SNF and are periodically updated throughout the SNF stay. The RUG assignment takes into account the patient’s diagnosis, performance of activities of daily living, and treatments. A PMV patient typically qualifies for the extensive service RUGs (“special/extensive” categories for activities of daily living 1 to 3), which have a typical reimbursement range of $300 to $400/d. However, it is a rare PMV patient whose actual cost of care can be covered at this reimbursement level.

SNFs are not usually staffed with full-time respiratory therapists and do not typically have daily physician assessments. PMV patients are high-risk patients for clinical decompensation, and should a high cost complication develop, eg, ventilator-associated pneumonia, deep venous thrombosis, central line infection, or nosocomial pressure wounds, the SNF typically transfers the patient to a STAC emergency department or to an LTAC hospital for stabilization, diagnosis, and treatment.

In most states, Medicaid programs (often responsible for up to 80% of long-term care patients) provide a daily SNF reimbursement of approximately $110/d, and thus SNF PMV care is simply not feasible. However, some states, such as Kentucky and North Carolina, have specific Medicaid rates for chronic, usually unweanable PMV patients that potentially may be adequate for a low-intensity, low-risk PMV patient in a SNF.

Home Health Care

A relatively small number of adult patients receive PMV at home under a home health care (HHC) contract. These patients typically have fewer comorbid conditions and are often receiving PMV for a nonpulmonary cause, eg, spinal cord injury, advancing amyotrophic lateral sclerosis or, increasingly, nocturnal ventilation via a permanent tracheostomy for obstructive sleep apnea. As outpatients, costs include physician office visits, visiting nurses, and the cost of equipment and supplies.

Under Medicare, a general process is followed. A physician writes an order for a home ventilator and related supplies as deemed necessary. A Healthcare Common Procedure Coding System code is generated and goes to a Durable Medical Equipment Regional Center for approval by a regional medical director. Physicians may find it necessary to discuss a patient’s needs with the medical director in order to get more expensive equipment approved.

A patient safety concern with financial implications is that most HHC PMV patients should have a back-up ventilator in the home. Medicare reimbursement rules, however, do not allow a back-up ventilator unless it is a portable ventilator that allows more patient mobility. HHC companies struggle to provide a satisfactory level of care at current reimbursement levels, and often the PMV patient does not have a financially or socially viable HHC/home ventilator option.

Recommendation 10

Financial managers of PMV-focused venues need to thoroughly understand the rules of PPS for both STAC and LTAC hospitals. The PPS system should be modified to eliminate financial incentives to delay or prevent discharge of PMV patients to lower cost venues. Admission to PMV-focused venues should be based on reasonable clinical criteria and not curtailed by arbitrary quotas designed to impose financial constraints.

Issue 11. What Would Be the Desired Characteristics of a PPS for PMV Care?

The assumption that the current PPS is the desired payment method for the PMV-focused venue
warrants examination. PPS assumes that the population of patients (PMV in this case) is homogeneous enough that an average patient in any setting can be cared for with an average, nationally determined payment. Therefore, PPS works best for high-volume, low-variability diagnoses, treated in settings where the provider cannot readily control access to care. The reality, however, is that PMV-focused venues rarely fit this model: they are usually low-volume facilities, serve patients with highly variable diagnoses and comorbidities; and have limited discharge options.

These unique features to PMV populations need to be addressed if a PPS is to operate appropriately. Possible approaches might include the following: (1) additional reimbursement for hospitals with dedicated PMV units (similar to subacute care units of the 1990s); (2) require all PMV patients to be treated within a given provider type, thus eliminating other provider sites from PMV treatment; (3) increase payments for higher-severity patients within a DRG; (4) segregate STAC hospitals into those with and without access to alternative venues, and provide different payments for each group; (5) develop admission criteria or guidelines for alternative venues so that PMV patients can be directed to the most effective least costly venue; (6) establish centers of excellence for PMV and establish financial incentives for patients to be transferred to them; and (7) regularly analyze incidence, prevalence, clinical acuity and actual costs of PMV care to ensure proper PPS reimbursement.

Under current Medicare policy, the “payment follows the provider,” and each provider receives a separate payment for its contribution to the patient’s entire episode of illness. There is an increasing dialogue in policy circles of the appeal of a policy in which the “payment follows the patient”. Under this construct, a payment is assigned to a patient’s episode of care and is divided among all provider sites of care, theoretically from STAC, through LTAC, SNF, rehabilitation, and home health. Obviously, this would be a very complicated system of administrative rules and financial risk; as of 2005, no realistic proposal has been made.

Another theoretically appealing but operationally difficult concept is to tie payment to some measure of quality. Under a “paying for performance” scenario, already in the embryonic stages in STAC, providers would receive higher or lower payments than the average Medicare payment for all DRGs based on aggregate performance against a set of quality measures in a small number of common disease states. In order to avoid the need for risk adjustment, these measures are often process measures that are associated with good outcomes (eg, receiving aspirin or β-blockers during a myocardial infarction), rather than specific outcome measures (eg, mortality from myocardial infarction). Any process measure must be scientifically well supported and applicable to the target population. Unfortunately, PMV patients are by definition distinct from patients receiving routine mechanical ventilation, and the literature guidelines for effective care are much less developed for PMV than for most other disease states

Recommendation 11

Leaders from various PMV-focused care venues should regularly explore with Medicare and other payers options for improving PPS.

Issue 12. What Opportunities for Research Will Best Inform the Conduct of Post-ICU Weaning?

The Brussels Roundtable, “Surviving Intensive Care," emphasized that the list of burdens with which patients leave the ICU is a long one.106 Late mortality, ongoing morbidity, neurocognitive defects, impaired mental health, poor functionality, decreased quality of life, decreased return to usual activities, stress on families and informal caregivers, and economic costs to the patient family and society are problems brought directly to post-ICU weaning. The stresses, physical and emotional, associated with continued weaning efforts, complications, worsened comorbidities, to name a few problems, add to the continuum of late sequelae.

The opportunities for research are many. The development of predictive models for both intermediate outcomes (eg, weaning success and hospital discharge) and long-term outcomes (ultimate survival, functional status and, costs) are foremost among them. Specific interventions (eg, weaning protocols, nutritional strategies, physical therapy techniques) need to be carefully assessed in properly done randomized multicenter trials with meaningful outcomes. Follow-up studies on implementation of therapies with proven benefit are also important. Finally, at the basic science level, studies on the mechanisms of chronic illness myopathy and other manifestations of chronic illness organ dysfunction are essential in order to understand how best to approach the chronically critically ill.

Recommendation 12

Clinical studies evaluating patient selection, care processes, and care settings with respect to long-term outcomes are clearly needed. Basic science
studies focused on the mechanisms of multiorgan dysfunction in the chronically critically ill are also important. Given the rapidly expanding PMV population, research funding sources should give a high priority to such studies.

APPENDIX

Conference Participants

Presenters: David Scheinhorn, MD (Barlow Respiratory Hospital); Paul Selekey, MD (Hoag Hospital); Douglas Gracey, MD (Mayo Clinic); David Nierman, MD (Mt. Sinai Medical Center); Kent Christopher, MD (University of Colorado); Scott Epstein, MD (Tufts New England Medical Center); David Chao, MD (Polly Ryan Hospital); Gerald J. Criner, MD (Temple University); Don Morran (The Morran Company); Shannon Carson, MD (University of North Carolina); Roger Goldstein, MD (West Park Healthcare Center); James Dudley, RRT; Vernon Vertelle, RRT (Apria); Neil MacIntyre, MD (Duke University, Moderator).

Sponsors: Thomas Buckingham and Mary Ellen Kleinheinz, MD (Select Medical Corporation); Denise Clark, RN, and Larry Wright, RRT (Tyco Puritan Bennett); Peter Doyle, Cheryl Needham, BA, RRT, Adam Seiver, MD, and William Funnis, MS, MBA (Respirronics); James Dudley, RRT, and Vernon Vertelle, MBA, RRT, CCM (Apria); Al Greene, RRT, and Steve Moore (Fischer and Paykel); Jim Holmuth and Frank Tapanes (Viasys Health Care); Brad Traverse (Acute Long Term Hospital Association); Christopher Logan, RRT (LifeCare Hospitals).

Other Participants: Sam Giordano, RRT, and John Walton, RRT (American Association for Respiratory Care); Meg Stearn-Hassenpflug, MS, RD (Barlow Respiratory Hospital); Eric Yaeger, MD, FCCP (American College of Chest Physicians); Ashok Kanohar Kamik, MD, FCCP (American College of Physicians); Jonathan Sevansky, MD (American Thoracic Society); Phillip Porte, Judah Skolnick, MD, and Steven Zimmet, MD (NAMDRC).

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