CRITICAL CARE ALERT®

A monthly update of developments in critical care and intensive care medicine

AHC Media LLC Home Page— www.ahcmedia.com

CME for Physicians— www.cmeweb.com; CE for Nurses— www.ceweb.com

AHC Media LLC

INSIDE

Financial Disclosure: *Critical Care Alert*'s editor, David J. Pierson, MD, nurse planner Leslie A. Hoffman, PhD, RN, and peer reviewer William Thompson, MD, report no financial relationships related to this field of study.

Should We Continue Using Erythropoietin in the ICU?

ABSTRACT & COMMENTARY

By Andrew M. Luks, MD

Pulmonary and Critical Care Medicine, University of Washington, Seattle

Dr. Luks reports no financial relationship to this field of study.

Synopsis: *This randomized, double-blind, placebo-controlled trial demonstrates that administration of erythropoietin once a week for three weeks does not reduce the incidence of red blood cell transfusion in a mixed population of critically ill patients but is associated with an increased incidence of thrombotic events and a possible decrease in mortality in trauma patients.*

Source: Corwin HL, et al. *N Engl J Med.* 2007;357(10):965-976.

Previous trials have demonstrated that administration of recombinant erythropoietin to critically ill patients decreases the need for red blood cell transfusions and leads to higher hemoglobin values. Building on these trial results, Corwin and colleagues conducted a prospective, multi-center, randomized, double-blind trial to determine whether administration of a reduced dose of the erythropoietin was safe and effective in a mixed group of critically ill patients. They recruited medical, surgical and trauma patients who were in the ICU for at least 48 hours and had hemoglobin levels less than 12 g/dL. Patients were excluded if they were expected to leave the ICU within a subsequent 48-hour period or had either active thrombotic disease such as acute coronary ischemia or pulmonary embolism, or a history of the same.

Between 48 and 96 hours after admission, patients were randomized to receive 40,000 units of subcutaneous erythropoietin or placebo once a week for three weeks. The medication was not given if the patient's hemoglobin was above 12 mg/dL at the intended administration time. The primary end-point was the percentage of patients receiving red blood cell transfusion between days 1 and 29 of the study. Secondary end-points included the number of units transfused, mortality at days 29 and 140 and the change in hemoglobin values from baseline to day 29. The need for transfusion was at the discretion of each patient's treating physician but the investi-

gators provided guidelines recommending that physicians target a hemoglobin value between 7 and 9 mg/dL and not transfuse patients with values above the upper limit of that range.

There were 1460 patients enrolled in the study — 733 in the erythropoietin group and 727 in the placebo group. The groups were well matched except for the fact that the trauma patients were significantly younger than either the medical or surgical ICU patients. In the erythropoietin group, 28% of patients received only one dose of the study medication, 32% of patients received two doses and 40% completed the entire three-week course.

There were no significant differences in the percentage of patients receiving transfusion (46% erythropoietin vs 48.3% placebo) or the number of units transfused in each group (4.5 + 4.6 vs 4.3 + 4.8 units). At day 29, the change in hemoglobin concentration was greater in the erythropoietin group than the placebo group (1.6 + 2.0 g/dL vs 1.2 + 1.8 g/dL) but by day 42, there were no significant differences in absolute hemoglobin concentrations. Mortality was lower among the patients treated with erythropoietin alfa (8.5% vs 11.4% at 29 days and 14.2% vs 16.8% at 140 days) with the largest differences in mortality seen in the trauma patients. There was an increased incidence of thrombotic events in the erythropoietin group (16.5% vs 11.5%, hazard ratio 1.4) with post-hoc analysis demonstrating that thrombosis largely occurred in those patients not on heparin prophylaxis.

Critical Care Alert, ISSN 1067-9502, is published monthly by AHC Media LLC, 3525 Piedmont Road., NE, Building. 6, Suite 400, Atlanta, GA 30305.

SENIOR VICE PRESIDENT/GROUP PUBLISHER: Brenda Mooney.

ASSOCIATE PUBLISHER: Lee Landenberger.

MANAGING EDITOR: Iris Young.

MARKETING MANAGER: Shawn DeMario

GST Registration Number: R128870672.

Periodicals postage paid at Atlanta, GA.

POSTMASTER: Send address changes to ***Critical Care Alert,*** P.O. Box 740059, Atlanta, GA 30374.

Back issues: $40.

Missing issues will be fulfilled by customer service free of charge when contacted within one month of the missing issues date.

This is an educational publication designed to present scientific information and opinion to health professionals, to stimulate thought, and further investigation. It does not provide advice regarding medical diagnosis or treatment for any individual case. It is not intended for use by the layman.

Subscriber Information

Customer Service: 1-800-688-2421

Customer Service E-Mail Address: customerservice@ahcmedia.com

Editorial E-Mail Address: iris.young@ahcmedia.com

World Wide Web: http://www.ahcmedia.com

Subscription Prices

United States

1 year *with* free AMA Category 1 credits: $289

Add $12.95 for shipping & handling.

(Student/Resident rate: $120)

Multiple Copies

Discounts are available for group subscriptions. For pricing information, please call Tria Kreutzer at (404) 262-5482.

Canada

Add GST and $30 shipping.

Elsewhere

Add $30 shipping.

Accreditation

AHC Media LLC is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians.

AHC Media LLC designates this educational activity for a maximum of 25 *AMA PRA Category 1 Credits™*. Physicians should only claim credit commensurate with the extent of their participation in the activity.

AHC Media LLC is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

This activity has been approved for 13.3 nursing contact hours using a 60-minute contact hour.

Provider approved by the California Board of Registered Nursing, Provider # 14749, for 13.3 Contact Hours.

This educational activity is intended for critical care physicians and nurses. It is in effect for 36 months from the date of publication.

AHC Media LLC

Questions & Comments

Please call **Iris Young,** Managing Editor, at (404) 262-5413 or e-mail at iris.young@ahcmedia.com between 8:30 a.m. and 4:30 p.m. ET, Monday-Friday.

COMMENTARY

The decision to use any treatment should always be driven by a consideration of the risk-to-benefit ratio. In light of the study by Corwin and colleagues, it does not appear that erythropoietin fares well in this analysis. Regarding the benefits, there is insufficient evidence of clinical utility; the study described above showed no significant differences in the use of red blood cell transfusions and no clinically meaningful changes in hemoglobin concentrations.

Although earlier trials by this group did show a benefit in this regard, it should be remembered that in one trial[1] erythropoietin decreased the need for transfusion by a very modest one unit over the course of admission, a difference of questionable clinical benefit. Supporters of erythropoietin use might point to the mortality benefit demonstrated in the trial described above, but the observed difference was largely restricted to the trauma patients and further work is necessary to confirm what can best be viewed as a preliminary result, particularly in light of a recent meta-analysis which showed no mortality benefit to erythropoietin administration.[2]

There is also reason for concern on the risk side of the equation. Earlier trials have shown evidence of increased thrombotic complications with higher doses of erythropoietin and the study by Corwin and colleagues now shows that even with administration of lower doses, there is still an increased risk of thrombotic events, particularly in those patients not on heparin prophylaxis.

When viewed in conjunction with the questionable clinical benefit, the increased risk of thrombotic events should prompt reconsideration of erythropoietin use in the care of critically ill patients. Future work may yet demonstrate further evidence of a mortality benefit as well as the reasons for such an effect, but until this work is complete, routine use of this medication is not warranted. ■

References

1. Corwin HL, et al. EPO Critical Care Trials Group. Efficacy of recombinant human erythropoietin in critically ill patients: a randomized controlled trial. *JAMA.* 2002;288:2827-2835.
2. Zarychanski R, et al. Erythropoietin-receptor agonists in critically ill patients: a meta-analysis of randomized controlled trials. *CMAJ.* 2007; [Epub ahead of print].

Barriers to Implementing the Leapfrog Group Recommendations for ICU Staffing

ABSTRACT & COMMENTARY

By David J. Pierson, MD, Editor

Synopsis: *In this survey of US hospitals, more than half did not have an identifiable ICU director. Loss of autonomy and income for admitting primary physicians were perceived as important barriers to implementation of the Leapfrog Group's ICU physician staffing guidelines.*

Source: Kahn JM, et al. *J Crit Care.* 2007;22:97-103.

This paper reports on a telephone survey of US non-rural hospitals and the physician directors of their ICUs. The authors sought to determine the extent to which the recommendations of the Leapfrog Group about ICU staffing had been implemented, and to clarify the reasons for delays in or resistance to such implementation.

Sites were selected at random from hospitals participating in the database maintained by the Committee on Manpower for Pulmonary and Critical Care Societies, which includes US hospitals nationwide. The investigators stratified their target ICUs according to hospital size and the population served, and classified the hospitals into either academic or community. Their survey addressed 4 domains with respect to the Leapfrog Group recommendations for intensivist staffing: knowledge and perceived utility of the recommendations, current compliance, potential barriers to implementing the recommendations, and possible solutions to these barriers. Seventy-two hospitals were surveyed in late 2003 and early 2004.

Among the 72 hospitals that were approached, 47 (65%) responded to initial telephone inquiries, and 26 (55%) of these did not have an identifiable physician ICU director. The ICU directors of the remaining 21 hospitals were interviewed. Eleven (52%) of these considered themselves very familiar with the recommendations. Of the 20 physician ICU directors who answered questions about their respective hospitals' Leapfrog compliance, 8 (40%) considered their units to be Leapfrog-compliant, although only 5 of these ICUs (25%) actually proved to be compliant with all 4 recommendations. Of the 15 directors not in compliance, 13 indicated motivation to become so in the future.

The most significant barrier to implementation of the recommendations was concern over loss of control for physicians who would no longer be providing care to critically ill patients. Loss of income and increased cost to hospital administration were other perceived barriers. Perceived measures of potential importance in overcoming these barriers included increasing the numbers of available intensivists, increasing funds from hospital administrators, and assistance from government and third parties.

COMMENTARY

The Leapfrog Group is a consortium of health care purchasers formed in 2000 to advocate for improved quality and safety in healthcare. For the ICUs of all US non-rural hospitals, the Leapfrog Group recommends the following as the standard for intensivist staffing:

- A board-certified or board-eligible intensivist physician should manage or co-manage all patients in the ICU;
- The intensivist should be present in the ICU during daylight hours, with no competing clinical duties;
- At other times, an intensivist should be able to return ICU pages within 5 minutes; and,
- Another physician, or a nonphysician extender such as a physician assistant or advance practice nurse certified in caring for critically ill patients, should always be available within 5 minutes of the ICU.

This study suggests that we are still a considerable way from implementing these recommendations. It points out a number of important barriers to such implementation, the most glaring of which is that over half of the hospitals surveyed did not even have an identifiable physician ICU director. As the authors point out, without an ICU director to bring about change, there seems little likelihood that the Leapfrog Group's recommendations for physician staffing can be put into effect.

The cost of hiring intensivists — even if enough of them were readily available, something regarded by many as doubtful — is obviously a key obstacle to be overcome. However, this study points out that there are other important barriers, such as fear of loss of control and income on the part of primary physicians if their ICUs became "closed" through implementation of the Leapfrog guidelines.

Although quite a bit has been published in this subject area, the available evidence supporting the Leapfrog recommendations is hardly definitive, and considerable controversy remains as to whether their implementation would in fact improve the quality of ICU care and/or

decrease adverse outcomes across the board. However, despite the limitations of this study, such as the small sample size and the fact that the survey was carried out 4 years ago in a rapidly evolving area, the message seems clear that major changes would have to take place in most US hospitals if the Leapfrog ICU recommendations were actually to be put into effect. ■

Adverse Effects of Restricted Resident Duty Hours on Patient Care, Education, and Faculty Satisfaction

ABSTRACT & COMMENTARY

By Leslie A. Hoffman, PhD, RN

Department of Acute/Tertiary Care, School of Nursing, University of Pittsburgh

Dr. Hoffman reports no financial relationship to this field of study.

Synopsis: *The majority of key clinical faculty reported worsening in continuity of care, physician-patient relationships, education and accountability due to restricted duty hours.*

Source: Reed DA, et al. *Arch Intern Med.* 2007;167:1487-1492.

THE GOAL OF THIS STUDY WAS TO ELICIT VIEWS OF key clinical faculty members regarding the effects of residency duty-hour limits on patient care, education, professionalism and faculty satisfaction. Key clinical faculty members were defined as active clinicians who dedicated at least 15 hours a week, on average, to teaching in an internal medicine residency program. Program directors were excluded. Participants were selected from a national sample of 39 residency programs chosen to reflect variations in program size and NIH funding.

Of 154 faculty members who were sent surveys, 111 (72%) responded. Most respondents (75%) had 5 or more years of teaching experience, and one-third had at least 15 years' experience. The majority reported worsening in the continuity of patient care provided by residents (87%), residents' communication with patients and families (66%), and the overall quality of patient care (60%) as a result of duty-hour limitations. In addition, they perceived decreased opportunities for didactic (69%) and bedside (73%) teaching, performing procedures (57%), and resident autonomy (57%). Approximately half (51%) perceived a decrease in professionalism. Conversely, they perceived an improvement in residents' well-being, including level of fatigue (85%) and life balance (81%).

Slightly more than half of key clinical faculty members (56%) reported decreased overall satisfaction with teaching and 33% reported a decrease in satisfaction with their careers as a result of duty-hour limits. A minority (40%) reported that they felt less able to develop mentoring relationships with students. Key clinical faculty who spent at least 15 hours a week teaching were more likely to report worsening of teaching opportunities (odds ratio [OR], 5.03, 95% CI, 1.77-14.33) and quality of care (OR, 2.38; 95% CI, 1.14-4.99) in the context of restricted resident duty hours.

■ COMMENTARY

Residency duty hour limits were implemented to reduce the risk of adverse events from sleep deprivation. While studies support an improvement in residents' well-being and quality of life, the impact on patient care and clinical teaching remains unclear. The impact on faculty workload and satisfaction is important because there are few rewards for good teaching beyond personal satisfaction. Teachers who are disillusioned are more likely to leave teaching and may not advocate their specialty to students.

In this study, clinical faculty believed that duty hour limits had negative effects on continuity of care, communication with patients and families, and the overall quality of care. This is not unexpected. At one hospital, efforts to comply with the change in rules led to an average of 15 handoffs per patient during a 5-day hospitalization. Each intern was involved in more than 300 handoffs during a month-long rotation, a 40% increase over that reported before duty-hour limits.[1] With 6 million patients receiving care in US teaching hospitals each day, the impact on patient safety is potentially huge.[1]

Teaching hospitals are admitting patients who are older and sicker and discharging them more quickly—factors that have increased the workload of residents and faculty, independent of duty hour limits. Educational programs require more trainee supervision, and faculty members are held accountable for patient length of stay as well as generating salary through billing. The patient care team is likely to include nurse practitioners, physician assistants, and/or hospitalists, factors that increase the number of individuals who need to be apprised of the current and revised management plan. These challenges also likely contribute to the perceived decrease in faculty satisfaction. It is important to address ways to improve faculty satisfaction, given the pivotal role clinical teaching plays in educating the care providers of tomorrow. ■

Reference

1. Okie, S. *N Engl J Med.* 2007;356:2665-2667.

Special Feature

What Benefits Do Physical Therapy Confer on Critically Ill Patients?

By Leslie A. Hoffman, PhD, RN

EXAMINATION OF PATIENT OUTCOMES BEYOND SURvival has become an important focus of critical care research in the last decade. A substantial body of literature supports the conclusion that patients who experience critical illness face a lengthy recovery, especially if the need for mechanical ventilation is prolonged.[1] There are also adverse psychosocial outcomes, including depression, post traumatic stress syndrome, and increased caregiver burden.[2] If patients are to recover to their prior functional status, they are likely to require an extended period of rehabilitation. This essay will discuss the barriers and benefits to instituting a mobility therapy protocol early in the recovery phase of critical illness.

Risk Factors

The best rehabilitative approach involves minimizing factors that predispose to muscle weakness and deconditioning and limiting the duration of mechanical ventilation. Several strategies for accomplishing this goal are shown in Figure 1 (below).[3]

Among these strategies, attempts to minimize weakness or deconditioning using mobility therapy have received the least attention.[4] An increasing body of evidence suggests that attention to such techniques can have substantial benefits in patients who require ICU admission.

Who Can Be Mobilized?

Critically ill patients are commonly viewed as "too sick" to tolerate any activity, and therefore best managed by sedation and rest. In a study designed to evaluate the safety and feasibility of early mobilization, Bailey, et al[5] began an activity protocol "early" in critical illness and continued this protocol until ICU discharge. Three criteria were used to define patient readiness to begin the protocol: neurologic, respiratory and circulatory. Neurologic criteria required that the patient respond to verbal stimuli (purposeful response). Respiratory criteria required an inspired oxygen fraction of less than 0.6 and positive end-expiratory pressure less than 10 cm H_2O. Circulatory criteria required absence of orthostatic hypotension and catecholamine drips.

Over one year, 103 patients participated in 1,449 activity events, defined *a priori* as sitting on edge of bed without back support (n = 233), sitting in a chair after transfer (n = 454), and ambulation with or without assistance (n = 762). Of these patients, the majority (89%) were on mechanical ventilation. Nine patients experienced an adverse event, all minor, such as falling to the knees without injury, a drop in blood pressure to < 90mm Hg, or a fall in oxyhemoglobin saturation to < 80%. Of importance in today's cost-conscious healthcare environment, the intervention was carried out in a budget-neutral manner by a team consisting of existing ICU staff (nurses, respiratory therapists, physical therapists and critical care technicians). Similar success in safely achieving early mobility has been reported by several other centers,[6-8] suggesting that, when patients meet criteria for stability, mobilization can

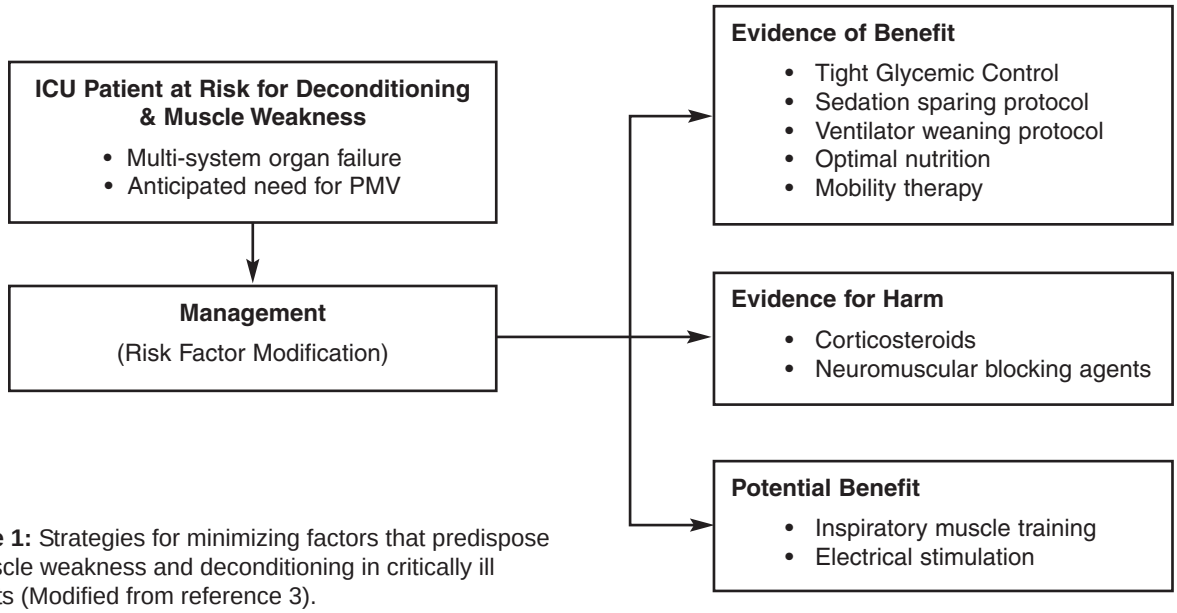

Figure 1: Strategies for minimizing factors that predispose to muscle weakness and deconditioning in critically ill patients (Modified from reference 3).

be safely begun early in recovery.

Passive activity also seems to have benefits. Griffiths et al[9] enrolled 5 critically ill patients who required neuromuscular blockade in a protocol wherein one leg of each patient was treated with continuous passive motion for three 3-hour periods daily for 7 days and the other leg received routine nursing care for 7 days. Continuous passive motion prevented atrophy and there was an 11% gain in fiber area compared with a 35% decrease in controls. Zanotti et al[10] compared the effects of active limb mobilization with or without electrical stimulation on muscle strength in 24 patients with COPD who remained bed-bound and ventilator dependent after 50 days in the ICU. Elective stimulation plus active limb mobilization improved muscle strength (p = .02) and shortened the time required to perform a bed-to-chair transfer (10.8 ± 2.4 vs. 14.3. ± 2.5 days; p =.001).

What are the Benefits and Risks of Early Mobility?

Potential benefits of mobility therapy include a decreased hospital and ICU length of stay,[6] higher level of functional ability at ICU discharge,[5] decreased time to wean on transfer to a long-term acute care setting,[11] and greater likelihood of discharge to home.[12] Morris et al,[6] from a study in which an ICU mobility team (RN, Nursing Assistant, Physical Therapist) rotated among 7 ICUs, reported that protocol patients (n = 150) experienced a shorter ICU length of stay (9.3 vs 10.3 days; p = .04) and hospital length of stay (14.4 vs 16.3 days; p =.008), compared to non-protocol patients. Bailey et al[5] reported that patients who began a mobility protocol in the ICU progressed faster in regaining functional ability after transfer to a rehabilitation unit.

You, et al[11] reported that patients who were able to perform rudimentary movements, such as rolling, scooting, or going from supine to sitting in bed, at admission to a long-term acute care facility were more likely to wean from mechanical ventilation (p < .04) compared to those without this level of functional ability. In 80 patients on PMV (≥ 7 days) we[12] identified three variables that predicted ability to return home at 6 months after ICU discharge; these were the Acute Physiology Score at ICU admission, functional ability at ICU discharge, and comorbidity.

There are also barriers to initiating early mobility.[4,13,14] ICU clinicians have concerns that early mobility might dislodge a vascular access device or the endotracheal tube. There is the potential that any additional movement, even passive exercise, will compromise oxygenation of hemodynamic parameters. The goal of maintaining the patient in a calm, pain-free and sedated state competes with the goal of early mobility. There are also concerns about the ability to justify the additional workload and costs, given the limited number of studies to date that provide evidence for benefit. A review of the limited evidence to date suggests that these concerns should not be viewed as obstacles, if appropriate patient selection, monitoring and timing are used.[4,13,14]

What can be Accomplished after Transfer from the ICU?

Mobility therapy is an important component of rehabilitation in long-term acute care and rehabilitation settings.[15-17] Martin et al[16] instituted a rehabilitation program for patients transferred to a ventilator weaning unit that included 30-60 minute sessions by a physical therapist 5 days a week; the sessions were provided during weaning trials if the patient could breathe for > 4 hours without ventilatory support. The initial phase of the program concentrated on posture and trunk control, following by standing and ambulation. Inspiratory muscle training was included if the patient could breathe independently for > 2 hours. Of interest, patients who weaned in 7 or fewer days had higher upper limb motor strength scores compared to those who required > 7 days to wean. Three variables were found to be significant in terms of weaning time: upper motor strength, exposure to neuromuscular blocking agents, and systemic steroids. Using regression analysis, an increment of 1 point in the upper extremity motor strength scale led to a reduction of ~ 7 days in weaning time.[16]

Several additional strategies are being tested to determine their ability to improve muscle function and, hence, ability to wean from mechanical ventilation. Patients who required prolonged mechanical ventilation (~ 50 days) and received inspiratory muscle training improved weaning success compared to patients who received a sham treatment (72% vs 40%, respectively).[18] Inspiratory muscle training consisted of 4 sets of 6-10 breaths through a threshold inspiratory muscle trainer at the highest setting tolerated 5 days a week until weaned or for 28 days.

Unanswered Questions

Despite these promising results, there continue to be many unanswered questions that create barriers to implementation of mobility therapy. Clearly, the primary concern is safety. More studies are needed to allay this concern. There is a deficit of information on the nature of muscle injury and muscle recovery following critical illness.[14] Consequently, it is difficult to develop protocols to reverse these deficits. Safety parameters need to be defined, as do optimal program components, duration and timing of therapy, and training to accomplish goals.

Summary

The concept that mobility therapy can hasten recovery is intrinsically appealing. However, there have been many ICU therapies that have had the same initial "box office appeal" but have failed to confer promised outcomes. More studies are necessary to better define the potential of this intuitively appealing means to improve long-term outcomes in chronically, critically ill patients. ■

References

1. Chelluri L, et al. Long-term mortality and quality of life after prolonged mechanical ventilation. *Crit Care Med.* 2004; 32:61-69.
2. Hopkins RO, et al. Two-year cognitive, emotional, and quality of life outcomes in acute respiratory distress syndrome. *Am J Respir Crit Care Med.* 2005;171:340-347.
3. Schweickert WD, Hall J.ICU-acquired weakness. *Chest.* 2007;131:1541-1549.
4. Morris PE. Moving our critically ill patients: Mobility barriers and benefits. *Critical Care Clinics.* 2007;23:1-20.
5. Bailey P, et al. Early activity is feasible and safe in respiratory failure patients. *Crit Care Med.* 2007; 35:139-145.
6. Morris PE, et al. A mobility protocol for acute respiratory failure patients delivered by an ICU mobility team shortens hospital stay (abstract). *Crit Care Med.* 2006;34:A20.
7. Zafiropoulos B, et al. Physiological responses to the early mobilization of the intubated, ventilated abdominal surgery patient. *Australian Journal of Physiotherapy.* 2004; 50:95-100.
8. Perma CS, et al. Early mobilization of LVAD recipients who required prolonged mechanical ventilation. *Texas Heart Institute Journal.* 2006;33:130-133.
9. Griffiths RD, et al. Effect of passive stretching on the wasting of muscle in the critically ill. *Nutrition.* 1995; 11:428-432.
10. Zanotti E, et al. Peripheral muscle strength training in bed-bound patients with COPD receiving mechanical ventilation. *Chest.* 2003;124:292-296.
11. You D, et al Does early mobility influence outcome of patients being weaned from prolonged mechanical ventilation? (abstract). Proceedings of the American Thoracic Society. 2006; 3:A41
12. Kim YY, et al. Characteristics associated with discharge to home following long-term mechanical ventilation: A signal detection analysis. *Res Nurs Health.* 2006;29:510-520.
13. Hopkins RO, et al. Transforming ICU culture to facilitate early mobility. *Critical Care Clinics.* 2007;23:81-96.
14. Morris PE, Herridge MS. Early intensive care unit mobility: Future directions. *Critical Care Clinics.* 2007; 23:97-110.
15. Nava S. Rehabilitation of patients admitted to a respiratory intensive care unit. *Arch Phys Med Rehabil.* 1998;79:849-854.
16. Martin UJ, et al. Impact of whole-body rehabilitation in patients receiving chronic mechanical ventilation. *Crit Care Med.* 2005;33:2259-2265.
17. Porta R, et al. Supported arm training in patients recently weaned from mechanical ventilation. *Chest.* 2005;2511-2520.
18. Martin AD, et al. Inspiratory muscle strength training in failure to wean patients: Interim analysis of a controlled trial (abstract). Proceedings of the American Thoracic Society. 2006;3:A41.

CME / CNE Questions

42. When compared to placebo, administration of 40,000 units of subcutaneous erythropoietin alfa once a week for three weeks is associated with which of the following outcomes?

a. Decreased need for transfusion
b. Lower hemoglobin values
c. Lower mortality in trauma patients
d. Higher mortality in patients with renal insufficiency
e. Decreased length of hospital and ICU stay

43. The study by Corwin et al demonstrated that once a week administration of erythropoietin alfa is associated with increased incidence of which of the following adverse events?

a. major bleeding events
b. ventilator-associated pneumonia
c. catheter-related sepsis
d. urinary tract infection
e. thrombotic complications

44. Which of the following were perceived by physician ICU directors to be barriers to implementation of the Leapfrog Group's recommendations for ICU staffing?

a. Potential loss of income to primary physicians
b. Loss of control over patient management by admitting primary physicians
c. Increased cost to the hospital administration
d. All of the above
e. None of the above

45. In the study of barriers to implementation of the Leapfrog Group's recommendations for ICU physician staffing, what proportion of hospitals surveyed had an identifiable ICU director?

a. 20%

b. 31%
c. 45%
d. 63%
e. 82%

46. Which of the following are included in the Leapfrog Group's recommendations for physician ICU staffing in non-rural hospitals?
a. a board-certified or board-eligible intensivist physician should manage or co-manage all patients in the ICU;
b. the intensivist should be present in the ICU during daylight hours, with no competing clinical duties;
c. at other times, an intensivist should be able to return ICU pages within 5 minutes
d. another physician, or a non-physician extender should always be available within 5 minutes of the ICU
e. all of the above

47. Which of the following were adversely affected by restricted resident duty hours?
a. continuity of care provided by residents
b. resident communication with patients and families
c. decreased resident autonomy
d. overall quality of patient care
e. all of the above

48. Key clinical faculty who taught in internal medicine residency programs reported all of the following as a result of duty-hour limitations except:
a. decreased opportunities for teaching
b. decreased satisfaction with teaching
c. No change in satisfaction with their careers
d. Worsening in the continuity of care
e. Worsening in communication with patients and families

49. Among 103 patients who received early mobility therapy in the ICU:
a. Nine patients experienced minor adverse events.
b. Upper arm strength improved 25% over baseline.
c. Benefits were greater in patients < 65 years of age.
d. Patients regained the ability to sit but not walk by ICU discharge.
e. Staff resistance prevented success of the program.

50. Potential benefits of mobility therapy include:
a. decreased hospital and ICU length of stay
b. higher level of functional ability at ICU discharge
c. decreased time to wean on transfer to a long-term acute care setting
d. greater likelihood of discharge to home
e. all of the above

Answers: 42 (c); 43 (e); 44 (d); 45 (c); 46 (e); 47 (e); 48 (c); 49 (a); 50 (e)

CME / CE Objectives

After reading each issue of *Critical Care Alert*, readers will be able to do the following:
- Identify the particular clinical, legal, or scientific issues related to critical care.
- Describe how those issues affect nurses, health care workers, hospitals, or the health care industry in general.
- Cite solutions to the problems associated with those issues.

In Future Issues:

Why Are We Giving Our Patients Blood?

PHARMACOLOGY WATCH

Supplement to Clinical Cardiology Alert, Clinical Oncology Alert, Critical Care Alert, Infectious Disease Alert, Internal Medicine Alert, Neurology Alert, OB/GYN Clinical Alert, Primary Care Reports, Travel Medicine Advisor.

Adult Immunization Guidelines from CDC Released

In this issue: *Updated Immunization Guidelines from the CDC; Do antivirals have a role in the treatment of Bell's palsy? Topiramate is a promising treatment for alcohol dependence; and FDA Actions.*

The *Annals of Internal Medicine* has published updated Adult Immunization Guidelines from the CDC as an early release article on their website dated October 18. Full guideline will be available in the November 20 print edition. The guideline has several important changes and updates.

The new herpes zoster vaccine is added to the guideline this year. The vaccine should be given routinely to all immunocompetent adults age 60 and older. It is not recommended for immunocompromised adults as it is a live attenuated virus. The vaccine is given once in a lifetime, and does not require a booster.

The new human papilloma virus has also been added. The vaccine protects against 4 types of HPV, which causes 90% of genital warts and 70% of cervical cancers. It is recommended for women aged 11 to 26 years. It requires three doses given at zero, 2 and 6 months. It should not be given to pregnant women.

The new pertussis vaccine is coupled with diphtheria and tetanus to form Tdap (Adacel- Sanofi Pasteur). This is a 1-time, 1-dose vaccine that should be given to all adults age 64 or younger when they are scheduled for their next tetanus (Td) booster. Tetanus boosters should be given every 10 years, but the interval may be shortened to as little as two years for high-risk patients including postpartum women, close contact of infants younger than 12 months of age, and all healthcare workers with direct patient contact. It has not been tested in adults age 65 or older. This vaccine is different from the previously approved Tdap for adolescents aged 10 to 19 (Boostrix-GlaxoSmithKline).

There are now 15 indications for influenza vaccine. New indications include those who have difficultly handling respiratory secretions or have increased risk of aspiration. All women who are pregnant or will be pregnant during the flu season should be vaccinated. All healthcare workers should be vaccinated unless they have strong contraindications.

Hepatitis B vaccine recommendations have changed, and the vaccine is now recommended for all sexually active adults who are not in a long-term mutually monogamous relationship.

Because of several recent large-scale mumps outbreaks in this country, a mumps vaccine booster is now recommended for specific age groups, especially adults who work in healthcare settings. The standard is to give MMR, even if immunity exists for one or more of the components of MMR.

The pneumococcal vaccine recommendations remain the same. The vaccine should be given at age 65 unless the patient has specific risk factors, in which case it should be given to those younger than 65. A small subgroup of patients should be given a second booster. If the vaccine was initi-

This supplement was written by William T. Elliott, MD, FACP, Chair, Formulary Committee, Kaiser Permanente, California Division; Assistant Clinical Professor of Medicine, University of California-San Francisco. In order to reveal any potential bias in this publication, we disclose that Dr. Elliott reports no consultant, stockholder, speaker's bureau, research, or other financial relationships with companies having ties to this field of study. Questions and comments, call: (404) 262-5431. E-mail: iris.young@ahcmedia.com.

ated under age 65 for high-risk patients, a booster should be given at age 65 or five years after the initial vaccine. If the vaccine was initiated over age 65, a booster should only be given to immunocompromised patients after five years. The vaccine should not be given every five years (a common misconception). In fact, no one should receive more than two doses under any circumstances. There is even some evidence that more than two doses may be harmful and could potentially attenuate the immune response.

Antivirals and Bell's Palsy?

Do antivirals have a role in the treatment of Bell's palsy? This question has been debated for decades, with several small studies indicating a relationship between herpes simplex infections and facial paralysis. Despite this, treatment with acyclovir or valacyclovir has not been proven to be effective in treating Bell's palsy. Regardless, antivirals are frequently prescribed along with oral steroids. A new study confirms that steroids are useful, but antivirals are not. Nearly 500 patients with new onset of Bell's palsy were randomized to 10 days of treatment with prednisolone, acyclovir, both agents, or placebo. The primary outcome was recovery of facial function. At three months, the proportion to patients who had recovered facial function were 83.0% in the prednisolone group compared with 63.6% among patients who did not receive prednisolone ($P < 0.001$) and 71.2% in the acyclovir group as compared to 75.7% among patients who did not receive acyclovir (adjusted $P = 0.50$). After nine months, recovery was 94.4% for prednisolone and 81.6% for no prednisolone ($P < 0.001$) and 85.4% for acyclovir and 90.8% for no acyclovir (adjusted P = 0.10). For patients treated with both drugs, recovery was 79.7% at 3 months ($P < 0.001$) and 92.7% at nine months ($P < 0.001$). There were no serious adverse effects in either group. The authors conclude that early treatment with prednisolone significantly improves the chance of complete recovery, while there's no evidence of benefit with acyclovir alone or in combination with the steroid (*NEJM*. 2007; 357:1598-1607).

Topiramate Promising for Alcohol Treatment

Topiramate is a promising treatment for alcohol dependence according to a new study. The drug was shown to be effective in this role in a small study published in 2003. This new, larger multisite 14 week double-blind, randomized, placebo controlled trial enrolled 371 men and women age 18 to 65 years who were diagnosed with alcohol dependence. Up to 300 mg per day of topiramate was given to 183 participants while 188 were treated with placebo. Both groups were enrolled in a weekly compliance enhancement intervention program. The primary end point was self-reported percentage of heavy drinking days, while secondary outcomes included other self-reported drinking measures along with laboratory measures of alcohol consumption. Topiramate was more efficacious than placebo at reducing percentage of heavy drinking days from baseline to 14 weeks (mean difference 8.44%; 95% CI, 3.07%-13 .80%; $P = .002$). Topiramate also reduced all of the drinking outcomes ($P <.001$ for all comparisons). Adverse events were more common with topiramate, including paresthesia (which occurred in over 50% of those on the drug), taste perversion, anorexia and difficulty with concentration. In general, however, the drug was safe and consistently efficacious for treating alcohol dependence (*JAMA*. 2007;298:1641-1651). An accompanying editorial points out that the benefits of topiramate were still increasing at the end of the study, indicating the longer treatment may be more effective (*JAMA*. 2007;298:1691-1692).

FDA Actions

The FDA has announced new warnings on phosphodiesterase type 5 inhibitors regarding hearing loss. The drugs include sildenafil (Viagra, Revatio), tadalafil (Cialis) and vardenafil (Levitra). The agency has received 29 cases of sudden hearing loss associated with use of the drugs dating back to 1996. Most cases were unilateral and temporary.

Modafinil (Provigil) has also been the subject of new warnings including serous rashes and psychiatric symptoms. The drug, which is used for narcolepsy, obstructive sleep apnea, shiftwork disorder, and multiple sclerosis, has been associated with severe rashes including Stevens-Johnson syndrome and toxic epidermal necrolysis. The FDA suggested caution should be exercised when modafinil is given to patients with a history of psychosis, depression, or mania.

An FDA advisory panel has recommended restricting childhood cold medications to children over the age of six years. They also recommend strong limits on marketing these products for younger children. This follows a voluntary withdrawal from the market of infant cough and cold medications by most manufacturers of these products. Voluntary withdrawal involves medications used in children younger than two years. The drugs that contain decongestants and antihistamines have been associated with more than one hundred deaths since 1969. ■