

# CRITICAL CARE ALERT®

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

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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.

## Growth of Intensive Care Unit Use and Costs

ABSTRACT & COMMENTARY

By Ruth Kleinpell, PhD, RN

Center for Clinical Research and Scholarship, Rush University Medical Center; Professor, Rush University College of Nursing, Chicago, IL

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

**Synopsis:** Through a retrospective analysis, this study examined ICU resource use and costs for 121,747,260 inpatient hospitalizations and found a rapid rise in Medicare ICU use with stable adjusted daily critical care costs, but increasing costs for care outside the ICU.

**Source:** Milbrandt, EB, et al. Growth of intensive care unit resource use and its estimated cost of Medicare. *Crit Care Med* 2008;36:2504-2510.

TRACKING THE UTILIZATION OF INTENSIVE CARE UNIT (ICU) resources is important in informing clinicians of patterns of use and costs of care, especially as the proportion of patients aged 65 and older increases and ICU resources remain limited. Milbrandt and colleagues examined resource use and costs for ICU and floor costs for inpatient Medicare prospective payment system hospitalizations during a 10-year period from 1994 to 2004. The findings of their retrospective review demonstrated that 33% of Medicare hospitalizations involved an ICU stay. Annual adjusted Medicare ICU costs increased 36% due to increased utilization. While adjusted ICU cost per day remained stable (\$2616 vs \$2575; 1994 vs 2004); adjusted floor cost per day rose due to decreased floor length of stay (\$1027 vs \$1488).

### COMMENTARY

Similar to other studies assessing ICU utilization,<sup>1-3</sup> the results of this study highlight that ICU use is on the rise and leading to large increases in annual ICU costs for Medicare. While the daily cost of ICU care remained relatively stable, average adjusted cost per floor day rose substantially due to reductions in floor length of stay, with the remaining days becoming more costly.

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This study demonstrated that efforts to reduce length of stay do not seem to have an appreciable effect in the ICU. The authors cite that interventions to decrease ICU length of stay such as the use of sedation and analgesia protocols, ventilator weaning, and intensivist staffing have the potential to reduce costs if widely applied in the ICU setting. ICU clinicians should be cognizant of the importance of targeted interventions aimed at improving care in the ICU with the goal of decreasing unnecessary ICU length of stay. Efforts to promote best care in the ICU, including the use of a daily goal sheet,<sup>4</sup> infection prevention measures, palliative care, and family care conferences<sup>5</sup> to discuss realistic treatment goals for critically ill patients, may help in decreasing ICU length of stay as well as ICU costs of care. ■

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# Is It Time to Jump off the Intensive Insulin Therapy Bandwagon?

ABSTRACT & COMMENTARY

By **Andrew M. Luks, MD**

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

**Synopsis:** *This single-center, randomized controlled trial demonstrated that intensive insulin therapy targeting blood glucose values of 80-110 mg/dL does not improve mortality, but does increase the incidence of hypoglycemia in a group of critically ill medical and surgical patients.*

**Source:** Arabi YM, et al. Intensive versus conventional insulin therapy: A randomized controlled trial in medical and surgical critically ill patients. *Crit Care Med* 2008;36:3190-3197.

ALTHOUGH THE ORIGINAL STUDY BY VAN DEN BERGHE **A**t et al sparked interest in the use of intensive insulin therapy in the ICU,<sup>1</sup> subsequent studies have cast doubt on the efficacy and safety of this practice.<sup>2</sup> Arabi and colleagues sought to further clarify these issues by comparing the use of intensive (IIT) and conventional (CIT) insulin protocols in a combined medical-surgical intensive care unit (ICU) patient population.

The authors conducted a randomized controlled trial in a combined medical-surgical-trauma ICU at a single institution. They included all ICU patients > 18 years of age with a serum glucose > 110 mg/dL within the first 24 hours of admission, and excluded all patients with Type 1 diabetes mellitus, diabetic ketoacidosis, documented hypoglycemia on the current admission, or a variety of other criteria. All included patients were started on an insulin drip (250 units Humulin® R insulin in 250 mL of 0.9% normal saline) and were then randomized to have blood glucose values maintained between either 80-110 mg/dL or 180-200 mg/dL. There was no blinding of the treatment assignment. Blood glucose val-

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## Questions & Comments

Please call **Paula Cousins**, Senior Managing Editor, at (404) 262-5468.



ues were initially monitored every hour with adjustments in the frequency of monitoring based on whether the patient had low or stable glucose values. The primary outcome variable was ICU mortality and secondary endpoints included hospital mortality, ICU and hospital length of stay, duration of mechanical ventilation, number of hypoglycemic events, the need for renal replacement therapy, and the incidence of ICU-acquired infections. These outcome variables were compared using t-tests, chi-square tests, and proportional tests and the analysis was based on the intention-to-treat principle.

A total of 523 patients were enrolled in the study, 266 in the IIT group and 257 in the CT group. The groups were well matched except the IIT group was younger and had less diabetes and lower inclusion blood glucose values. The average daily insulin dose was  $71.2 \pm 50.2$  units in the IIT group and  $31.4 \pm 42.4$  units in the CIT group. The average glucose level was  $115 \pm 18$  mg/dL in the IIT group and  $171 \pm 34.2$  mg/dL in the CIT group. There were no differences in mortality between the IIT and CIT groups (13.5% vs 17.1%;  $P = 0.30$ ), but IIT was associated with a higher incidence of hypoglycemia (defined as blood glucose  $< 40$  mg/dL), with 28.6% of the IIT patients experiencing at least one episode of hypoglycemia compared to only 3.1% in the CIT group. Patients who had hypoglycemia had higher ICU mortality than those who did not (23.8% vs 13.7%); in subgroup analysis, IIT was associated with decreased mortality in patients with BMI  $< 26.2$  kg/m<sup>2</sup> or APACHE II  $< 22$  and increased ICU mortality in patients with GCS  $< 9$ . There were no differences between IIT and CIT in any of the other secondary endpoints.

#### ■ COMMENTARY

Even though it was a single-center trial involving only surgical patients, the study by van den Berghe et al provoked a sea-change in ICU practice marked by the widespread adoption of intensive insulin therapy protocols in both medical and surgical ICU patients.<sup>1</sup> This bandwagon effect was similar to that seen after single trials showed possible benefits from recombinant activated protein C and corticosteroid therapy in patients with septic shock. The data from Arabi and colleagues, along with a growing literature on the topic, suggest it may be time to jump off the IIT bandwagon and reevaluate our current practices. Granted, the current study was a non-blinded trial at a single institution with only 21 ICU beds, but the results are in line with those of other recent trials demonstrating that intensive insulin therapy with tight glucose targets is associated with an increased incidence of hypoglycemia and/or no clear mortality benefit.<sup>2,3</sup> Whether these protocols should be

abandoned altogether is not clear from these studies, but the increased incidence of hypoglycemia, which is being increasingly documented in these and other trials, suggests that we should at a minimum move away from protocols with strict glucose targets of 80-110 mg/dL and instead accept more modest goals of glucose values in the mid-100 mg/dL range and focus on avoiding severe hyperglycemia. ■

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## Improving Palliative Care in the ICU

ABSTRACT & COMMENTARY

By Ruth Kleinpell, PhD, RN

**Synopsis:** A quality improvement intervention aimed at improving palliative care in the ICU resulted in improvements of nurse-assessed quality of dying and a reduction in ICU length of stay, but no changes in family perceptions of quality of dying or satisfaction with care.

**Source:** Curtis JR, et al. Integrating palliative and critical care: Evaluation of a quality-improvement intervention. *Am J Respir Crit Care Med* 2008;178:269-275.

THIS STUDY REPORTS ON THE RESULTS OF A SINGLE-hospital study of a quality improvement intervention to improve palliative care in the ICU. An interdisciplinary intervention designed to improve the ability of ICU clinicians to provide palliative care focused on providing clinician education through the use of a teaching video, poster boards, and pamphlets; training of ICU champions on palliative care concepts in a half- or full-day training session; and the use of family satisfaction data to provide feedback to the ICU team. The intervention occurred over a 10-month period. Family members of patients who died in the ICU after a minimum stay of

6 hours before death or within 24 hours of transfer to another hospital location from the ICU were surveyed 4-6 weeks after the patient's death. ICU nurses who cared for the patients were surveyed within 48 hours of the patient's death. Responses from 275 family members revealed no significant improvement in family-assessed quality of dying or satisfaction with care, but responses from 523 nurses demonstrated significant improvements in nurse-assessed quality of dying and a reduction in ICU length of stay through the integration of palliative care in the ICU.

#### ■ COMMENTARY

Palliative care focuses on symptom management, promoting treatment based on patient and family preferences, and facilitating care for patients with life-threatening illness and their families with a focus on comfort and quality of life.<sup>1</sup> Palliative care is increasingly being integrated into the care of patients in the ICU. There is growing recognition that integrating palliative care in the ICU is beneficial for patients with complex symptom management issues or with end-of-life care, as well as for their family members.

A number of national initiatives have focused on improving palliative care in the ICU, including the Center to Advance Palliative Care ([www.capc.org/palliative-care-across-the-continuum/intensive-care-unit](http://www.capc.org/palliative-care-across-the-continuum/intensive-care-unit)), the Robert Wood Johnson Foundation program for promoting palliative care excellence in the ICU ([www.promotingexcellence.org](http://www.promotingexcellence.org)), and the American College of Critical Care Medicine,<sup>2</sup> among others.

Interventions and strategies for improving palliative care in the ICU have specifically focused on improving communication, promoting family involvement, utilizing interdisciplinary team rounds, creating a supportive ICU culture for end-of-life care, and integrating palliative care consultations in the ICU.<sup>2-4</sup>

The results of this study show that focused efforts to integrate palliative care through the use of an interdisciplinary intervention designed to improve ICU clinicians' ability to provide palliative and end-of-life care in the ICU were beneficial in decreasing length of stay and in quality of dying ratings by nurses. This study contributes to the body of literature on integrating palliative care in the ICU and indicates that additional focus on providing direct interventions to family members may be needed to improve family perceptions of quality of care. The study did not demonstrate improvements in family perceptions of the quality of dying or in family satisfaction ratings, and it is evident that additional research is indicated to further explore the impact of interventions addressing palliative care on family members. ■

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## Having the Right Tool: A Highly Visible Angle Indicator Improved HOB Elevation

ABSTRACT & COMMENTARY

By **Leslie A. Hoffman, PhD, RN**

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University of Pittsburgh

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

**Synopsis:** A highly visible angle indicator placed on ICU beds increased compliance with 30° head-of-the-bed elevation from 23% to 72%.

**Source:** Williams Z, et al. A simple device to increase rates of compliance in maintaining 30-degree head-of-bed elevation in ventilated patients. *Crit Care Med* 2008;36:1155-1157.

THE PURPOSE OF THIS STUDY WAS TO DETERMINE whether use of a simple, easy-to-view, color-coded device could increase adherence to head-of-bed (HOB) elevation guidelines. The device consisted of a piece of glossy printer paper cut into a triangle. The base of the triangle was colored red (right half) or green (left half). A silk suture was fastened to the apex of the triangle and a steel nut tied to the distal end of the suture. The angle indicator was placed on the bed so that the weight hung in the green zone when the HOB was elevated > 30° and in the red zone when elevated < 30°.

The study was conducted over 4 weeks. During the first 2 weeks, nursing staff were e-mailed to remind them of the HOB elevation policy and  $> 30^\circ$  HOB orders were written by the medical staff. Over the next 2 weeks, the device was placed on the bed of all surgical, medical, thoracic, and trauma ICU patients who did not have an indication to be kept in a less elevated position. A total of 268 HOB elevation measurements was taken.

The average HOB elevation without the device was  $21.8^\circ$  ( $n = 166$ ) and with the device  $30.9^\circ$  ( $n = 102$ ) ( $P < 0.005$ ). When compliance was defined as  $\geq 28^\circ$  elevation, 23% of beds without the device were in compliance, compared to 72% with the device. The majority (72%) of nurses found the device to be an improvement over existing methods, 88% found it helpful, and 84% felt it should be routinely used.

#### ■ COMMENTARY

Findings of this study support the adage that a simple solution can be very effective and, in this example, incur minimal cost. The authors note that their study was independently funded at a material cost of \$42. Prior studies indicate poor adherence to recommendations for  $30^\circ$  HOB elevation despite strong supporting evidence, published national recommendations, and educational initiatives that promote this strategy as a means of preventing ventilator-associated pneumonia (VAP). The challenge is to determine ways to insure that guidelines are consistently implemented and preventable complications avoided. Congress has observed that some characteristics of our current reimbursement system can be viewed as allowing a negative incentive—hospitals that improve patient safety and decrease preventable complications see their revenues and, consequently, their profit decreased.

In 2005, Congress instructed the Secretary of Health and Human Services to select at least 2 conditions that are: a) high cost or high volume or both; b) result in the assignment of a case to a diagnosis-related group (DRG) that has a higher payment when present as a secondary diagnosis; and c) could reasonably have been prevented through the application of evidence-based guidelines.<sup>1</sup> The Centers for Medicare and Medicaid Services selected eight conditions that were deemed preventable complications that no longer qualify for reimbursement. Additional conditions, possibly including VAP, will likely be added in the future. Hence, the intervention described in this study is of great interest.

In the control phase of the study, the authors were unable to demonstrate compliance with HOB elevation despite standardized orders to maintain the HOB  $> 30^\circ$ , the presence of traditional HOB indicators, and in-serv-

ice teaching. Lack of knowledge was not an issue, as 94% of those surveyed indicated they were aware of the importance of maintaining adequate HOB elevation. Prior studies indicate that ICU clinicians overestimate the angle of elevation and commercial angle indicators are often small and not highly visible. The angle indicator used in the present study was clearly visible from the patient's doorway, clearly displayed whether the bed was adequately elevated using a color-coded (red/green) indicator and accurate in Trendelenburg position. As such, it seems a particularly cost effective way to promote adherence to HOB guidelines. ■

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## Special Feature

# End-of-life Decision Making: An Evidence-based Approach

By Leslie A. Hoffman, PhD, RN

WHEN CRITICAL ILLNESS OCCURS, THE PRIMARY GOAL is to assist patients to survive the acute threat to their lives. This goal is commonly achieved with 75%-90% of patients who are admitted to an intensive care unit (ICU) surviving to discharge.<sup>1</sup> However, surveys also indicate that approximately 20% of all deaths in the United States occur during or after admission to an ICU.<sup>2</sup> Following admission, it is important to insure that all appropriate care is provided and, at the same time, to be vigilant regarding the possibility that recovery consistent with patient values and preferences is no longer possible. This essay explores steps that can be taken to make this difficult transition easier for clinicians, patients, and families.

#### What Is Known about Communication?

Studies indicate that less than 5% of patients who are critically ill can participate in decision-making regarding their values and preferences.<sup>3</sup> Consequently, the family is often placed in the role of surrogate decision-maker. This role can be challenging. Studies indicate that a substantial number of caregivers experience significant emotional distress, including anxiety, depression, or post-traumatic stress disorder, and are at risk for

increased mortality.<sup>3</sup> In a multicenter study that surveyed 920 family members 48 hours after patients had been admitted to a pediatric or adult ICU, 69% of family members reported symptoms of anxiety and 35% reported symptoms of depression.<sup>4</sup> In a study that followed 41 family members for 3-12 months after the death of a patient in the ICU, more than one-third had at least one psychiatric illness, including major depression disorder (27%), generalized anxiety disorder (10%), or panic disorder (10%).<sup>5</sup> The challenge, therefore, is to identify ways to ease this burden.

#### What Increases Family Satisfaction?

**Opportunities to Share Concerns.** When recovery may not be possible, it is common to schedule a family conference to discuss options and learn family values and preferences. Studies indicate that family conferences may not be fully achieving this goal. From a study enrolling 214 family members, 51 different families and 36 different physicians, findings indicated that physicians spoke 71% of the time and families 29% of the time.<sup>6</sup> Increased time speaking on the part of families was associated with increased satisfaction with physician communication and decreased ratings of conflict with the physician. In this study, missed opportunities fell into three categories: 1) to listen and respond to the family; 2) to acknowledge and address family emotions; and 3) to pursue key principles of medical ethics and palliative care, such as the exploration of patient preferences, explanation of surrogate decision making, and affirmation of non-abandonment.<sup>6,7</sup>

**Open Visiting Hours.** Although open visiting hours have been identified by families as an important need, a recent regional survey conducted in New England, found that only 32% of ICUs followed this policy.<sup>8</sup> Of these, the majority (66%) were non-teaching hospitals. The study also surveyed nurses in these ICUs and reported substantial resistance to open visiting hours. Based on focus-group input, nurses viewed open visiting hours as interfering with their ability to provide care, decreasing control over the environment, and promoting family anxiety due to the extent of time spent in the unit. The authors advocated several possible solutions, including staff education regarding the benefits of greater patient involvement for families and education directed toward improving communication skills when interacting with families. A recent qualitative study reported examples of family presence as calming and helpful during weaning from prolonged mechanical ventilation, beneficial in improving surveillance (e.g., detecting changes, raising concerns, and asking questions of clinicians), as well as a potential hindrance to

the weaning process depending on individual family members' actions.<sup>9</sup> Communication skill training may be a means of assisting staff to use strategies that optimally promote the benefits of family presence.

**Timely Knowledge of Prognosis.** Family members typically want to be informed about changes in the patient's condition, to be updated regarding the prognosis, and to have their questions answered honestly in terms that they can understand.<sup>3</sup> When family conferences were audiotaped, comments indicated that physicians shared prognoses about quality of life and functional outcomes in almost all conferences. However, prognosis for survival was discussed only about one-third of the time. Less well educated families received the least amount of information about prognosis.<sup>10</sup> This observation raises the possibility that less educated family members may be at risk for misunderstanding the gravity of the situation. However, the study provided no insight into whether providing prognostic information about survival would alter satisfaction.

#### What Should Be Communicated?

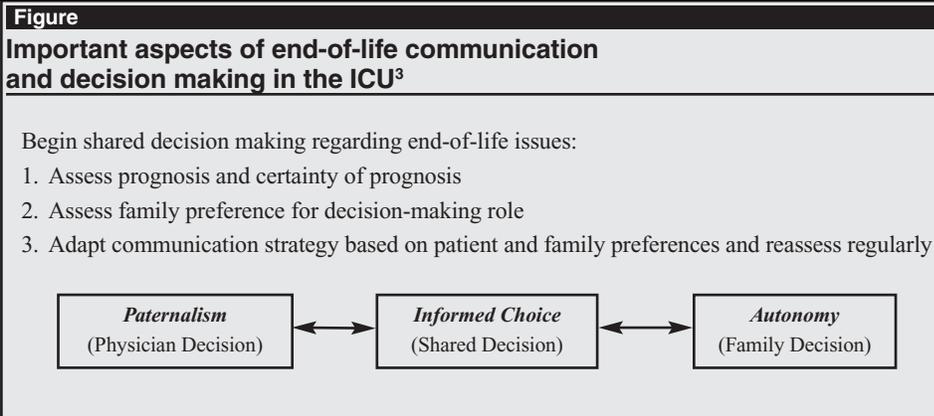
Curtis suggests a structured approach to end-of-life decision making based on a summary of available evidence and consensus of opinion:<sup>3</sup>

1. Physicians have an obligation to disclose information about a patient's medical condition and prognosis.
2. Family members are an important source of information about the patient's values and preferences.
3. Family members should be counseled to use the principle of substituted judgment to guide decisions regarding what the patient would want.

Curtis developed the conceptualization illustrated in the Figure (page 79) to depict differences in the way family members wish to be involved in end-of-life decision-making.<sup>3</sup> In this conceptualization, preference ranges from paternalism (physician makes the decision with limited family input) to autonomy (family makes the decision with limited or no physician input) with a middle range that involves informed choice and joint decision making (shared decision). He advocated that discussions with the family be preceded by an assessment of the patient's prognosis and its certainty, an assessment of family communication preferences, and communication strategies based on this information. Because family preferences can change, the process includes periodic reassessment. This approach avoids a "one size fits all" approach.

#### Strategies to Make Communication More Effective

Few studies have tested interventions designed to better prepare families for withdrawal of life support.



Although limited, evidence is emerging that suggests ways to make this difficult time easier for families before and after life support withdrawal.

**Family Conferences.** Prior studies suggest that strategies can make family conferences more effective. As noted previously, it is important to allow family members time to share their questions and concerns. If several members of the health care team will be present, it is helpful to have a “pre-conference” to insure that there is consensus within the interdisciplinary team with regard to goals of the conference, patient prognosis, and what treatments are indicated or not indicated. Statements that acknowledge the difficulty family members are experiencing are important, as well as clear statements that indicate that the patient will not be abandoned and will be kept comfortable. Additional suggestions are included in the Table (right).

**Access to Written Information.** Kirchhoff randomized 22 participants to receive printed information about what to expect during withdrawal of life support or to usual care without this information.<sup>11</sup> When contacted by telephone 2-4 weeks later, families in the intervention group expressed greater satisfaction with the information they were provided. The usual-care group reported having to ask for information, not being prepared, and not understanding that time to death can be different for different patients. Rather than being emotion-provoking, the printed information proved to be comforting, based on questionnaire responses and unsolicited comments. The additional step of providing such information is a simple but important means of potentially decreasing grief and depression after the event.

**Protocols to Promote Consistent Communication.** Mosenthal et al randomized families of 286 patients admitted to a trauma ICU to an intervention—consisting of a palliative care assessment within 24 hours of ICU admission, which encompassed an assessment of the likely prognosis, advance directives, family needs, and surrogate decision-making concerns, and an interdisci-

plinary family meeting within 72 hours of ICU admission regardless of prognosis during which the likely outcomes, management, and goals of care were discussed—vs usual care, which consisted of family meetings and counseling by bereavement specialists on an “as-needed basis.”<sup>12</sup> Compared to usual care, rates of mortality, do-not-resuscitate orders, and withdrawal of life support did not change. However, do-

not-resuscitate orders were instituted earlier and intervention patients had a shorter ICU and hospital length of stay. There was also a change in the qualitative content of rounds, reflected in more frequent discussions about pain and symptom management and goals of care.

In this study, several components of the intervention (bereavement support, family meetings) were already in use before the intervention was initiated. However, they were implemented in an ad hoc manner, typically when the patient was judged to be terminal. The intervention caused these components to become a standard part of ICU care and resulted in a significant culture change, as evidenced by more frequent discussions of pain and symptom management and goals of care. As with weaning from mechanical ventilation, the major factor causing the change appeared to be a protocol that required a systematized approach for all patients and their families.

<b>Table</b>
<b>Making family conferences about end-of-life decisions more effective<sup>3</sup></b>
<ol style="list-style-type: none"> <li>1. Identify a private place for the conference.</li> <li>2. Hold a preconference to reach consensus on goals among members of the interdisciplinary team.</li> <li>3. Spend more time listening than talking.</li> <li>4. Include emphatic statements that acknowledge the following: <ul style="list-style-type: none"> <li>• the difficulty of having a critically ill loved one</li> <li>• the difficulty of surrogate decision making</li> <li>• the difficulty of losing a family member</li> <li>• the importance of focusing on patient values and preferences</li> <li>• that the patient and family will not be abandoned</li> <li>• that patient comfort will be assured.</li> </ul> </li> <li>5. Provide explicit support for the decisions made by the family.</li> </ol>

## Summary

An emerging body of evidence suggests that it is possible to improve the experience of ICU admission for families by implementing strategies that promote timely and open communication and greater access to the patient. Families appear to differ in their wishes for involvement in end-of-life decision making and may change preferences for involvement during the course of the illness. Several studies suggest that relatively minor changes in the way care is delivered can have a significant impact on family satisfaction. These include providing written information regarding what can be expected during withdrawal of life support and implementing a protocol that ensures a palliative care assessment and interdisciplinary team conference within 72 hours of ICU admission for all patients. Further testing is indicated to determine if these positive findings can be replicated in other settings. ■

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## CME/CNE 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.

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8. Lee MD, et al. Visiting hours policies in New England intensive care units: Strategies for improvement. *Crit Care Med* 2007;35:497-501.
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11. Kirchhoff KT, et al. Preparing families of intensive care patients for withdrawal of life support: A pilot study. *Am J Crit Care* 2008;17:113-121.
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## CME/CNE Questions

36. Annual adjusted Medicare ICU costs were found to increase due to which of the following factors?
  - a. Increased utilization
  - b. Increased ICU length of stay
  - c. Increased ICU costs of care
  - d. Increased use of invasive ICU treatments
  - e. Increased ICU resource use
37. In the study by Arabi and colleagues on intensive insulin therapy (IIT) in the a combined medical-surgical ICU, what percentage of patients in the IIT group experienced an episode of hypoglycemia (blood glucose < 40 mg/dL)?
  - a. 3%
  - b. 10%
  - c. 28%
  - d. 45%
38. Which of the following outcomes was associated with a palliative care intervention aimed at improving ICU clinicians' ability to provide palliative and end-of-life care?
  - a. A decrease in the number of vasopressor days
  - b. Faster weaning from mechanical ventilation
  - c. Shorter ICU length of stay
  - d. Improved family satisfaction
  - e. Improved symptom management
39. Strategies for improving family satisfaction include:
  - a. open visiting hours.
  - b. access to written information about withdrawal of life support.
  - c. palliative care assessment/interdisciplinary care conference.
  - d. providing opportunities to share concerns
  - e. All of the above

Answers: 36. a, 37. c, 38. c, 39. e.

# 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.*

## JUPITER: C-reactive Protein a Marker for CV Events?

**In this issue:** The JUPITER trial causes a stir; ACP practice guideline for antidepressant use; testosterone for low libido; continued shortage of Hib vaccine; FDA Actions.

### **The JUPITER trial causes a stir**

Elevated high-sensitivity C-reactive protein (CRP) may help identify otherwise healthy patients with normal cholesterol levels who will benefit from statin therapy, according to the JUPITER trial published in November. Researchers randomized nearly 18,000 healthy men and women with normal cholesterol levels (LDL < 130 mg/dL) with CRP levels of 2.0 mg/L or greater to rosuvastatin (Crestor) 20 mg daily or placebo. The combined primary endpoint was myocardial infarction, stroke, arterial revascularization, hospitalization for unstable angina, or death from cardiovascular cause. The trial was stopped early at 1.9 years when the rate of the primary endpoint was found to be 0.77 per 100 person-years in the treatment group vs 1.36 per 100 person-years in the placebo (HR 0.56; 95% CI, 0.46-0.69;  $P < 0.00001$ ). Overall, the rate of events was low in both groups: 142 of 8901 in the treatment group vs 251 of 8901 in the placebo group. The individual endpoints of myocardial infarction, stroke, and revascularization or unstable angina were all reduced by approximately 50% in the rosuvastatin group, LDL cholesterol levels were decreased by 50%, and CRP levels were decreased 37%. There was not a significant increase in myopathy or cancer in the treatment group, but there was a higher incidence of physician-reported diabetes. The authors conclude that in apparently healthy persons without hyperlipidemia but with elevated

CRPs, rosuvastatin significantly reduced the incidence of major cardiovascular events (*N Engl J Med* 2008;359:2195-2207).

In an accompanying editorial, Mark Hlatky, MD, Stanford University School of Medicine, points out that although the relative risk reductions in the JUPITER trial were clearly significant, the absolute difference in risk was less impressive with 120 participants treated for 1.9 years to prevent one event. It is also difficult to know the role of CRP in risk stratification since patients with normal CRP levels were not treated and it is possible that lowering cholesterol with statins may benefit even those with low CRP levels. CRP may have a role in deciding whether to treat patients with intermediate risk, but it may be too early to use it to recommend treatment for those at low risk. Hlatky writes that "guidelines for primary prevention will surely be reassessed on the basis of the JUPITER results, but the appropriate size of the orbit of statin therapy depends on the balance between the benefits of treatment and long-term safety and cost" (*N Engl J Med* 2008;359:2280-2282). It is safe to say that JUPITER has been the subject of many lively discussions in hospital lunchrooms

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across the country. Whether the benefit of rosuvastatin can be generalized to all statins, whether CRP should be a standard part of yearly blood panels for adults patients, and whether everyone with an elevated CRP should be offered treatment with a statin are all questions that are being hotly debated and will need further evaluation.

### **ACP treatment guideline for antidepressants**

The American College of Physicians has issued a practice guideline for the use of antidepressants to treat depressive disorders. The guideline encompasses the use of newer "second-generation antidepressants," including the SSRIs: fluoxetine (Prozac), sertraline (Zoloft), paroxetine (Paxil), citalopram (Celexa), escitalopram (Lexapro), and fluvoxamine (Luvox). Also included were the SNRIs venlafaxine (Effexor), and duloxetine (Cymbalta), as well as other drugs such as mirtazapine (Remeron), bupropion (Wellbutrin), nefazodone, and trazadone. After reviewing 203 clinical trials, the guideline group concluded that there were no significant differences between the drugs with regard to efficacy. The guideline group recommends that second-generation antidepressants should be selected on the basis of adverse effect profiles, cost, and patient preference. They further recommend that clinicians should assess patient status, therapeutic response, and adverse effects of antidepressant therapy on a regular basis beginning within 1-2 weeks of initiation of therapy and that treatment should be modified if the patient does not have an adequate response to pharmacotherapy within 6-8 weeks. Finally, they recommend that clinicians continue treatment for 4-9 months after a satisfactory response in patients with a first episode of major depressive disorder. For patients with history of depression, a longer duration of therapy may be beneficial (*Ann Intern Med* 2008;149:725-733).

### **Testosterone for low libido: Questions remain**

Low sexual desire is commonly reported by postmenopausal women. A new study suggests that testosterone replacement may be of benefit. Researchers randomized 814 postmenopausal women with hypoactive sexual desire or disorder to testosterone patches delivering 150 or 300 mg of testosterone per day or placebo. The primary endpoint was change from baseline to week 24 in the 4-week frequency of satisfying sexual episodes. Safety outcomes were followed out to one year. At 24 weeks the primary endpoint was significantly greater in the group receiving 300 mg of testo-

sterone per day than placebo (increase in sexually satisfied episodes of 2.1 vs 0.7,  $P < 0.001$ ) but not in the group receiving 150 mg per day. Both doses of testosterone were associated with significant increases in desire and decreases in distress. The rate of androgenic side effects including unwanted hair growth was higher in the group receiving 300 mg per day. Breast cancer was diagnosed in 4 women who received testosterone vs none in the placebo group. The authors conclude that a testosterone patch delivering 300 mg per day results in modest but meaningful improvement in sexual function although the long-term effects of testosterone including effects on the breasts remain uncertain (*N Engl J Med* 2008;359:2005-2017). This study confirms previous reports that testosterone has a positive effect on sexuality in women. The rate of breast cancer, although not reaching statistical significance in this study, raises concern.

### **Continued shortage for Hib vaccine**

The continued shortage of the *Haemophilus influenzae* type b (Hib) vaccine has not led to an increase in *Haemophilus* infections according to the *MMWR*. It has been a year since the CDC recommended deferring the fourth dose of the Hib vaccine in healthy children (at 12-15 months of age) because of a shortage due to contamination concerns in the manufacturing process. Merck & Co. now reports that mid-2009 is a realistic date for normal production. The CDC has undertaken national surveillance for Hib infections including 748 cases in children < 5 years old. Of these, only 6% were clearly identified as serotype b (the most invasive strain of *Haemophilus*), although serotyping information was missing in nearly 40% of cases. The CDC is concerned because antibody levels fall 12 months after vaccination in children. In the U.K., where the fourth booster was not initially recommended, Hib infections rebounded after 12-15 months. CDC is recommending vigilance on the part of pediatricians and also is emphasizing that state and hospital labs should perform serotyping on all *Haemophilus* infections.

### **FDA Actions**

The FDA has approved fesoterodine fumarate for the treatment of overactive bladder. The drug relaxes smooth muscle of the bladder reducing urinary frequency, urge to urinate, and sudden urinary incontinence. Fesoterodine fumarate will be available in 4 mg and 8 mg strengths for use once daily. The drug is manufactured by Schwartz Pharma and will be marketed as Toviaz. ■