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INSIDE

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Surveillance for Ventilator-associated Pneumonia (VAP) Using Electronic Data Compared Closely with Clinician Detection

ABSTRACT & COMMENTARY

By Leslie A. Hoffman, PhD, RN

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

Synopsis: *An algorithm applied to electronic data detected 20 of 21 cases of possible ventilator-associated pneumonia in 459 patients, in accordance with CDC criteria.*

Source: Klompas, M, et al. *Infect Control Hosp Epidemiol.* 2008;29:31-37.

USING THE CRITERIA OF THE CENTERS FOR DISEASE Control and Prevention (CDC) to detect ventilator-associated pneumonia (VAP) is labor intensive and subjective. The goal of this study was to determine if the efficiency and objectivity of VAP surveillance could be improved by adapting CDC criteria to a format that allowed evaluation via an electronic clinical database. A total of 459 consecutive patients who received mechanical ventilation for a total of 2,540 days in 3 surgical and 2 medical ICUs in an academic medical center were enrolled in the study. VAP surveillance was performed using two methods: CDC criteria and an algorithm developed by the research team.

CDC criteria for VAP detection require that the patient fulfill 1 radiographic, 1 systemic, and 2 pulmonary criteria. The algorithm redefined assessment in a manner that allowed electronic monitoring. As examples, "new, progressive or persistent infiltrate" was redefined as "opacity, infiltrate, or consolidation that appears, evolves, or persists over ≥ 72 hours" and "worsening gas exchange, increased oxygen requirements or increased ventilatory demand" was redefined as "a sustained rise in ventilator settings relative to baseline." Baseline was defined as the patient's lowest setting after 48 hours or more of

decreasing ventilator support. This decision was based on the rationale that ventilator settings are typically reduced as the patient recovers; therefore, a 48-hour sustained increase would suggest a complication.

The algorithm detected 20 (95%) of the 21 VAP cases. All cases identified by the algorithm met CDC criteria (100% positive predictive value). One additional case was not identified by the algorithm. In this situation, ventilator change criteria were not sufficient to meet criteria in the algorithm. In comparison, clinicians identified 17 (81%) of the 21 cases.

■ COMMENTARY

Patients and politicians are increasingly advocating that hospitals provide data regarding their infection rates as a means of evaluating the quality of care. The "de facto" standard for identifying VAP is the definition published by the CDC. This definition is labor intensive and, hence, expensive to implement because it incorporates clinical criteria that require frequent detailed assessment at the bedside. CDC criteria are also subjective as they include statements such as "worsening gas exchange," "increased respiratory secretions," and "increased suctioning requirements."

The authors posited that routinely collected electronic clinical data could be used to increase the efficiency, objectivity, and reproducibility of VAP surveillance. The algorithm developed retained the central structure of CDC criteria, but was adapted in ways that allowed electronic monitoring based on radiology reports, laboratory values, and trend data. The algorithm was quite effective, identifying 20 of 21 cases of VAP. VAP surveillance had a higher positive predictive value and identified more cases than a prospective survey by clinicians. Although clinicians identified a majority of confirmed cases of VAP (17 of 21), only about half of the 33 cases they identified met formal CDC criteria. This error apparently resulted from incomplete knowledge of CDC criteria. For example, one patient met CDC criteria for hospital-acquired pneumonia but was not ventilated for 48 hours before onset of pneumonia and therefore did not meet VAP criteria. The single case of VAP missed by the algorithm met all criteria except for a sufficient increase in ventilator settings.

Use of this algorithm is attractive because it allows the capture of cases of VAP in a manner that is not labor intensive or subjective. It could easily be used as a clinical surveillance system to alert practitioners to likely cases of VAP or to provide trend data regarding the incidence of this complication. The major limitation to its use appears to be the requirement for an electronic data gathering system that systematically records and updates the necessary data. ■

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Which Mode Is More Comfortable: Pressure Support or Volume-control Continuous Mandatory Ventilation?

ABSTRACT & COMMENTARY

By David J. Pierson, MD, Editor

Synopsis: *In a small group of fully-alert, clinically stable patients with modest ventilation requirements, who were recovering from acute respiratory failure, most of them preferred pressure-support ventilation targeted to a tidal volume of 8 mL/kg over volume-control continuous mandatory ventilation at the same tidal volume.*

Source: Betensley AD, et al. *Respir Care.* 2008;53(7):897-902.

In this study from Henry Ford Hospital in Detroit, investigators sought to determine whether

pressure support ventilation (PSV) targeted at the same delivered tidal volume was more comfortable for patients than volume-control continuous mandatory ventilation (VC-CMV). In their 44-bed medical ICU and over a 13-month period, they screened 118 patients who were recovering from acute respiratory failure, of whom 19 met their criteria of being awake and alert, off all sedation for 12 hours or more, receiving a stable inspired oxygen fraction of 0.40 or less for at least 24 hours, with oxyhemoglobin saturation of 90% or more, and hemodynamically stable without requirement for pressors. Five of the 19 qualifying patients declined to participate, and 14 patients were studied.

All patients were initially ventilated using pressure-regulated volume control (PRVC). They were asked to quantitate their baseline level of comfort using a 100-mm visual analog scale extending between 0 ("Not at all comfortable") and 100 ("Very comfortable"). They were then ventilated for 30 minutes using either PSV (set to match end-inspiratory plateau pressure on PRVC and producing a tidal volume of 8 mL/kg) or VC-CMV (at the same tidal volume, with inspiratory:expiratory ratio 1:3 and square-wave inspiratory flow), in random sequence with a 30-minute interval period on PRVC. Patients rated their comfort levels on the visual analog scale at the conclusion of each 30-minute experimental period.

The 14 patients (mean age 65, 79% female) were recovering from congestive heart failure (5 patients), pneumonia (3), COPD or asthma (3), and other medical illnesses, and had been ventilated for 5.4 ± 5.0 days prior to being studied. Eleven patients indicated that they found PSV more comfortable than VC-CMV. Mean (SD) analog scale values for all the patients were 62.2 (18.0) on the baseline PRVC, 69.6 (17.8) on VC-CMV, and 83.2 (11.0) on PSV (difference between PSV and VC-CMV, $p = 0.02$). The 3 patients who did not find PSV more comfortable than VC-CMV were the ones who required the highest pressure support levels in the study (21, 26, and 26 cm H_2O) in order to achieve the target tidal volume of 8 mL/kg.

■ COMMENTARY

Previous studies have shown PSV to be more comfortable to patients than VC-CMV during noninvasive ventilation. In the present study, Betensley et al have shown for the first time, in a highly selected group of medical patients, that PSV was perceived by most patients to be more comfortable than VC-CMV during invasive mechanical ventilation.

These findings were obtained in a group of patients with little resemblance to those in whom the issue of comfort (ie, tolerance, and avoidance of dyssynchrony) comes up most often, at least in my practice. Even in the authors' ICU, these patients (less than 10 patients screened each month in a 44-bed ICU, and only 12% of screened patients actually studied) represented a small minority of those receiving mechanical ventilation in the unit. Which mode to use is often an issue early in the ICU course, when patients are most seriously ill. In such circumstances, comfort, or the lack thereof, is usually assessed by the bedside clinician rather than by the patient, using signs such as tachycardia, restlessness, tachypnea, breath-stacking, and the appearance of excessive effort used in triggering breaths or exhaling. Studying patients who were convalescing from critical illness and clinically stable was made necessary by the method used — assessing the patients' perceptions using a visual analog scale— and this needs to be kept in mind as the results of this study are interpreted.

Ever since the initial comparisons of intermittent mandatory ventilation with VC-CMV in the 1970s, studying different ventilator modes has been a tricky business. There are so many potential variables to compare and control — airway pressures (peak, plateau, mean); compliance and other measures of respiratory system mechanics; minute ventilation; arterial PO_2 or PCO_2 — that it has been difficult to impossible to satisfy critics that the settings were not chosen deliberately (or inadvertently) to favor a particular mode. Blinding is rarely possible, and seldom have such studies been performed by investigators who were not proponents of one of the modes or strategies being examined. It is therefore not surprising that so few good studies have been published in this field.

Betensley and colleagues are to be commended for trying very hard to compare PSV and VC-CMV under conditions that were as equivalent as possible. They have demonstrated that, in the patients selected and under the experimental conditions, PSV was generally the more comfortable mode. Could PSV have been set up differently, making the patients less comfortable breathing on this mode? Probably. Could VC-CMV have been set up in such a way that the patients liked it better than they did — for example, with decelerating inspiratory flow or a different I:E ratio? Possibly. For now, though, this is the best study available to clinicians who must contend regularly with the issue it addresses. ■

MRSA Screening in The ICU: Nares and Skin Are Not Enough

ABSTRACT & COMMENTARY

By David J. Pierson, MD, Editor

Synopsis: *In this single-center cohort study, 7% of ICU patients were colonized with MRSA on admission. In 34% of the positive cases, MRSA was detected by throat or rectal swabs but not by cultures of the anterior nares and other keratinized areas.*

Source: Batra R, et al. *Intensive Care Med.* 2008 (May 24); epub ahead of print

This prospective cohort study was carried out in a 30-bed medical-surgical ICU in London to determine whether culturing throat and rectal swabs would identify more cases of methicillin-resistant *Staphylococcus aureus* (MRSA) colonization than just swabbing at keratinized skin carriage sites such as the anterior nares, perineum, and axillae. Swabs from all these sites were cultured routinely in all patients on admission to the ICU during a 15-month period. The authors also cultured wounds and clinical specimens obtained during the first 48 hours in the ICU.

Complete sets of culture data were obtained from 1470 out of the 1480 consecutive adult patients admitted during the study period. One-hundred and five patients (7%) had MRSA recovered on admission to the unit. Among these MRSA-colonized patients, 63 (60%) had the organism recovered on pooled keratinized skin-site swabs (anterior nares, perineum, and axillae). In 36 other patients (34%), MRSA was detected only by throat and/or rectal swabs. Throat and rectal swabs combined had a higher sensitivity (76%) than pooled keratinized skin swabs (60%; $p = 0.02$). Five of the 105 patients had MRSA detected only from wounds, and not from any of the other sites.

■ COMMENTARY

Surveillance cultures for MRSA are recommended by current international infection-control guidelines for all patients in high-risk areas, including the ICU. Using barrier protection, isolation, cohorting, and surface decolonization procedures, both transmission of colonization and the incidence of clinical nosocomial MRSA infections can be reduced. However, consensus is lacking about the best sites or combination of sites to culture in detecting MRSA colonization, with the anterior nares the most commonly used site. This study shows that culturing the anterior nares, even when specimens are combined with swabs from other keratinized areas such as the perineum and axillae, will still miss a substantial number of cases. Its findings support the addition of throat and/or rectal swabs for routine surveillance cultures, but also remind us that even when all these sites are swabbed it is also important to culture any wounds that may be present, as MRSA may be recovered only from the latter in a certain number of cases. ■

Should We Transfuse Patients with Subarachnoid Hemorrhage?

ABSTRACT & COMMENTARY

By Andrew M. Luks, MD

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

Synopsis: *Although anemia was predictive of adverse outcomes in patients with aneurysmal subarachnoid hemorrhage, red blood cell transfusion was also associated with an increased risk of death, severe disability or delayed infarction. These results call into question the practice of liberal transfusion thresholds in patients with spontaneous subarachnoid hemorrhage.*

Source: Kramer AH, et al. *Crit Care Med.* 2008;36: 2070-2075.

Delayed ischemic insults are a major cause of morbidity and mortality in spontaneous subarachnoid hemorrhage (SAH). Recognizing this risk, some clinicians have argued that patients with SAH should be transfused to target hemoglobin levels of 9-10 g/dL in an effort to maintain oxygen delivery. In light of other studies demonstrating adverse outcomes with red blood cell (RBC) transfusion, Kramer and colleagues sought to determine what effect, if any, anemia or transfusion had on patient outcomes in spontaneous SAH.

The authors conducted a single-center retrospective cohort study. Patients who developed spontaneous SAH from a ruptured cerebral aneurysm over a 4-year period were included in the analysis while those patients in whom life-sustaining care was withdrawn within 72 hours of admission were excluded. One of the authors reviewed all of the records to collect information such as nadir hemoglobin concentrations, RBC transfusions, and a large number of other variables. Patients were reportedly managed according to "published guidelines." Anemia was defined as a hemoglobin concentration below 10 g/dL while vasospasm was thought to be present if patients had (1) a change in neurologic status not explained by another etiology; (2) vascular imaging interpreted by a neuroradiologist as demonstrating radiographic vasospasm and; (3) symptoms that were sufficiently severe for physicians to start treatment. The primary outcome was a combined endpoint of death, severe disability or delayed infarction with neurologic outcomes assessed at 6 weeks using the Glasgow Outcome Scale. Secondary outcomes included development of nosocomial infections and ARDS. A variety of statistical analyses were used to make comparisons between transfused and non-transfused patients and between anemic and non-anemic patients.

There were 245 patients included in the statistical analysis. Eighty-five patients (35%) were transfused an average of 2.5 units of blood with mean pre-transfusion hemoglobin concentrations of 9.5 g/dL (range 7-13). Both anemia and transfusion were associated with an increased risk of the combined primary endpoint (odds ratio for anemia: 2.7, 95% CI: 1.5-5; odds ratio for transfusion 4.8, 95% CI: 2.5-9.1). When both variables were included in the logistic regression model, transfusion, but not anemia, was still associated with an increased risk for the combined endpoint. The relationship between anemia and the combined endpoint was stronger among those patients with vasospasm (OR 3.8) whereas for transfusion, the odds ratio for the combined endpoint was higher among those patients who did not have vasospasm (OR 3.5). There was no association between transfusion and the subsequent diagnosis of vasospasm. Transfusion had no effect on the development of ARDS but was predictive of the development of nosocomial infections. The duration of blood storage had no effect on outcomes.

■ COMMENTARY

This is another study in a growing line of recent studies examining the impact of RBC transfusions on patients with various forms of critical illness. It is noteworthy that although anemia was associated with poor outcomes in patients with spontaneous SAH, transfusions were as well. Given that the relationship between anemia and adverse outcomes was stronger among those patients who were diagnosed with vasospasm while the relationship between transfusion and adverse outcomes was stronger among those patients without vasospasm, the paper suggests that rather than applying a single transfusion strategy to all of our SAH patients, we should possibly be tailoring our transfusion practices based on their clinical course and, in particular, whether or not they are having vasospasm.

In considering the results and their implications, however, several issues must be considered. This was a single center retrospective study and, as a result, may not be as applicable as the prospective randomized trial by Hebert and colleagues[1] that established current transfusion practices in critically ill patients. The fact that this is a single center study is particularly important in light of the discipline involved in the study. Although the authors stated that they adhered to "published guidelines" for the management of their patients, there is little in the way of randomized controlled data to guide the care of patients with SAH. In fact, only a single intervention in this patient population, nimodipine prophylaxis for vasospasm, has randomized controlled data to support its use while "Triple-H" therapy (hemodilution, hypertension, hypervolemia), one of the mainstays of vasospasm management, has little, if any, in the way of supporting evidence.[2] As a result, there is considerable inter-institution and inter-physician variability in the care of SAH patients and it is possible that similar effects of anemia and transfusion might not be seen in a multi-center setting, particularly if different transfusion practices are used at other institutions. The mean pre-transfusion hematocrit in this study, for example, was 9.5 g/dL, a high threshold that may not be used across all institutions.

Nevertheless, the results of this paper are generally consistent with those of many recent papers looking at the impact of RBC transfusions in critically ill patients. As a result, we need to stop treating SAH like it's the "heart attack of the brain" and transfusing all of these patients as we would someone with acute coronary syndrome. More restrictive practices may be warranted until further studies can be completed on this issue. ■

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SPECIAL FEATURE

Does Intensivist Management Improve Patient Outcomes in The ICU? A New Study Suggests Otherwise

By James E McFeely, MD

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

Introduction: Many Previous Studies Support Management by Intensivists

A large body of literature has developed over the last decade consistently showing improved outcomes with increased use of critical care physicians in the management of patients in the ICU. While many of these studies consist of retrospective reviews with relatively modest numbers of patients, the results have all been similar, consistently showing reductions in mortality, length of stay, resource use, and/or complication rates. The results have been so similar across disciplines that fewer such articles have appeared recently, as the questions seem to have been answered satisfactorily. However, a recent article reviewing the project IMPACT national database of ICU patients has come to a startlingly different conclusion and suggests that the underlying assumptions linking improved care and outcomes to critical care trained physicians need to be revisited.[1]

Articles documenting improved outcomes with change to an intensivist-led ICU date back to the late 1990s. For example, one retrospective review comparing outcomes of esophageal surgery patients showed a significant reduction in mortality (14 vs 6%, *p* .012) and a reduction in complications (55 vs 44%, *p* 0.002) after changing to intensivist management in a surgical ICU.[2] In another study involving a surgical ICU, the addition of daily rounds by an intensivist physician was associated with improved outcomes for abdominal aortic aneurysm patients: mortality declined (odds ratio 3.0; 95% confidence interval 1.9-4.9), and there were improvements in cardiac arrest rates, sepsis, renal failure and re-intubation rates.[3]

Other studies showed similar results. Adding a neurointensivist to a neurosciences ICU was associated with reductions in mortality, ICU length of stay, and rates of discharge to skilled nursing facilities.[4] Similar results were seen in a medical ICU after change to a closed model of care, including reduction in hospital and ICU length of stay, decreased days on a ventilator, and no significant change in mortality.[5] In the most-often cited systematic review of research in this area, published in 2002, researchers analyzed 26 relevant articles that all pointed to reduction in mortality and length of stay when the ICU goes from an open to a closed format.[6]

The New Study And Its Findings

Now, Mitchell, Levy and colleagues have published their analysis of the project IMPACT national database of ICU patients, examining the association between hospital mortality and management by critical care physicians.[1] The IMPACT database was studied for the years 2000 through 2004, and included data on more than 140,000 patients, admitted to 123 ICUs in 100 different US hospitals. The management characteristics of the various ICUs were divided into three categories: those in which 95% of patients were managed by critical care physicians (23 units); those in which less than 5% were managed by critical care physicians (21 units); and the majority of the units falling somewhere in between (79 units), with critical care physicians available but used at the discretion of the primary physician. Approximately 30,000 patients were excluded due to missing data for variables of interest; a further 5,000 patients were excluded who had mixed styles of management during their hospital stay.

The primary outcome variable was hospital mortality. Expected mortality was determined using the SAPS II probability of mortality, modified to improve the fit with the data set. An independent score was developed using a logistic regression model to measure propensity that a patient would be selected for critical care management, along with a logistic regression subset analysis for groups of patients where a high mortality would be expected (such as patients with respiratory failure at time of admission, patients transferred from another hospital, and patients transferred from the operating room).

Some of the study's results were predictable. For example, ICUs in which critical care physicians managed 95% or more of the patients tended to be larger and exist in larger hospitals. These hospitals were also more likely to have academic affiliation and to be training hospitals for critical care fellowships. Additionally, patients managed by critical care physicians for their entire length of ICU stay tended to have a higher severity of illness as estimated by the

SAPS II score than patients who did not receive critical care physician management. Patients treated by critical care physicians tended to receive more interventions (including ICU procedures, intravenous drugs, and ventilatory support), were less likely to be postoperative patients, and were more likely to be admitted from other hospitals, than in ICUs where critical care physicians were not available.

The unexpected result of this study was that actual hospital mortality was higher than predicted by the SAPS II score where patients were managed by critical care physicians and lower than predicted in ICUs where critical care physician management was not an option. The standardized mortality ratio for patients who received critical care in ICUs that managed 95% or more patients was 1.09 (95% CI, 1.05 to 1.13), compared with a standardized mortality ratio of 0.91 (CI, 0.88 to 0.94) for patients who did not receive critical care in ICUs in which critical care physicians managed 5% or fewer patients. Similar results were obtained when the data were further divided by SAPS-determined probability of death and by the propensity score that the patient was managed by a critical care physician. Even after accounting for these two measures of severity of illness, the critical care management mortality ratio was higher than predicted in almost all the subgroups analyzed. The authors' understated conclusion was that "despite adjustment for severity of illness, we cannot demonstrate any survival benefit with management by critical care physicians."[1]

Why Might These New Results Be Different?

These results are surprising, and at first blush are completely contradictory to the literature that preceded this article over the last ten to 20 years. Although it is difficult for the average clinician to assess and respond to these results because of the specifics of the statistical manipulation of the data, it is nevertheless clear that the authors intended to control for variables that we would all agree are relevant, such as severity of illness, patient likelihood of being selected for critical care management, and nesting of patients in specific ICU types that result in inter- and intra-ICU variability.

The authors pose several possible explanations for their results. They note that patients in the critical care management group received more ICU procedures and interventions, which in turn might be likely to result in complications which could affect mortality adversely. Another possible explanation is that despite their valiant attempts to control for co-founding variables, residual severity of illness metrics that would affect outcomes were not included in their scoring systems.

Other variables should be considered that the authors do not mention. For example, not all intensivist-managed ICUs are alike. The IMPACT database does not distinguish ICUs that have 24/7, on-site critical care physicians from those in which the patient is nominally managed by a critical care physician who makes rounds once a day, then turns over care to a hospitalist or nursing staff. Perhaps no "dose" effect was seen because many of the critical care managed units in this study had an insufficient intensivist presence to affect the mortality outcome. It may also be that hospitals that were able to participate in project IMPACT are not representative of ICUs in general. Of the thousands of ICUs in the United States, only 123 were participating in IMPACT at the time of this study. Presumably these were institutions that had both the resources and time to support data collection and pay the fee to participate in the database.

Apart from these general considerations, the most interesting group in this study is the 23 ICUs without critical care medicine coverage. These ICUs had minimal to no critical care resources available to them and yet had better than expected mortality outcomes. This subgroup of hospitals absolutely requires further study.

Possible explanations include the likelihood that these smaller ICUs tend to care for less sick patients. They tend not to have house staff and perform fewer ICU procedures, which may result in decreased complication rates. The remainder of the critical care team, if only through sheer practical necessity, may have developed techniques and procedures to make up for the lack of critical care physician input. In addition, smaller hospitals may have protocolized many aspects of ICU patient management and have better adherence to bundles of care. They may have taken the best of the critical care literature and applied it to their patient population without requiring the direct intervention of an on-site intensivist. Certainly the "low-hanging fruit" of improved ICU mortality (for example ventilator bundle, RT-directed weaning from mechanical ventilation) is available to non-intensivist physicians as well as to intensivists.

Where Do We Go from Here?

The Levy paper should provoke a substantial reassessment within the critical care community regarding the value that we bring to our hospitals and our patients. Although it is only one data point against many concerning the possibility that critical care physicians do not improve hospital mortality, it raises many questions that can and should be systematically answered. In particular it points to ICUs that are without the support of critical care medicine physicians yet appear to be doing a very good job of caring for their patients.

Indeed, the most important single outcome of this article might well be the identification of this group of units and the motivation to more fully understand how they go about their business. ■

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CME / CNE Questions

21. An algorithm designed to detect ventilator-associated pneumonia (VAP):

a. detected 20 of the 21 cases of VAP.
b. was more effective than housestaff in detecting VAP.
c. was less effective than experienced clinicians in detecting VAP.
d. was successful in detecting VAP in surgical, but not medical patients.
e. was more labor intensive to use as it required hand data entry.

22. In the study of MRSA colonization among patients admitted to the ICU, what proportion of MRSA-positive patients would have been detected if only the anterior nares and other keratinized skin areas had been swabbed?

a. 20%
b. 30%
c. 40%
d. 60%
e. 80%

23. In the study comparing pressure support with volume-control continuous mandatory ventilation, which patients preferred the latter?

a. Patients with the highest inspiratory pressure requirements in pressure support.
b. Patients with acute lung injury or the acute respiratory distress syndrome.
c. The majority of patients.
d. Patients who were not fully awake and able to use a visual analog scale.
e. None of the above.

Answers: 21 (a); 22 (d); 23 (a)

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:

Noninvasive Ventilation in Myasthenic Crisis

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.

Defining Diagnosis and Management of Prediabetes

In This Issue: Guidelines for prediabetes from The American College of Endocrinology; statins for the prevention of dementia? Possible help for women suffering from sexual side effects while on antidepressants; government incentives for electronic prescribing; FDA Actions.

The American College of Endocrinology has issued its Consensus Statement on the diagnosis and management of prediabetes. The guideline was prompted by evidence that complications of diabetes begin early in the progression from normal glucose tolerance to frank diabetes. They define impaired fasting glucose (IFG) as a fasting glucose 100-125 mg/dL, and impaired glucose tolerance (IGT) as 2 hour post glucose load 140-199 mg/dL. (Diagnostic for diabetes are fasting levels ≥126 mg/dl and post challenge ≥ 200 mg/dL). The guideline recommends intensive lifestyle management for pre-diabetes patients, including weight reduction by 5-10%, regular moderate-intensity physical activity for 30-60 minutes daily at least 5 days a week, a diet low in total saturated fat and transfatty acids, adequate dietary fiber along with low sodium intake, and avoidance of excess alcohol. Although they acknowledge that there are no approved pharmacologic therapies for prevention of diabetes there is evidence that both metformin and acarbose may reduce the rate of development of diabetes from prediabetes. There are safety concerns with thiazolidinediones and they must be used with caution. Persons with prediabetes should have the same lipid goals of those with established diabetes, including statin therapy to achieve LDL cholesterol, non-HDL-cholesterol, or apoB treatment goals of 100 mg/dl, 130 mg/dL, and 90 mg/dL respectively. Other lipid-lowering drugs may be used as considered appropriate. Niacin should be used with caution because of its potential to raise blood sugar. Blood pressure control should also be at the same targets as recommended for diabetics including systolic blood pressure <130 and diastolic less than 80 mmHg. ACEI/ARB should be first-line agents, with CCBs as appropriate second line treatment approaches. Thiazides, beta-blockers, or their combinations should be used with caution due to adverse effects on blood sugar. Antiplatelet therapy with aspirin is recommended for all persons with prediabetes who have no contraindications for aspirin. The full guideline can be found online at www.aace.com/meetings/consensus/hyperglycemia/hyperglycemia.pdf.

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Statins and Dementia

Do statins help prevent dementia and cognitive impairment? The medical literature has been conflicting on this issue, but now a new study from the University of Michigan raises hope that there is benefit. In a population-based cohort study, 1674 older Mexican Americans who were free of dementia or cognitive impairment at baseline were studied over 5 years. Overall, 27% of the participants took statins during the study. After adjusting for education, smoking status, genetic testing, and history of stroke or diabetes at baseline, persons who had used statins were about half as likely as those who did not to develop dementia or cognitive impairment (HR = 0.52; 95% CI 0.34-0.80). The authors conclude that statin users were less likely to have incident dementia or cognitive impairment without dementia during a 5-year follow-up. They also suggest that these results add to the emerging evidence suggesting a protective effect of statin use on cognitive outcomes (*Neurology.* 2008; 71: 344-350).

Help for Women on Antidepressants Who Suffer from Sexual Side Effects

Women with antidepressant related sexual side effects improved with sildenafil (Viagra) according to a new study. In the 8-week randomized double-blind placebo-controlled trial, 98 women who were stabilized on a serotonin reuptake inhibitor were randomized to sildenafil or placebo at a flexible dose starting at 50 mg adjustable to 100 mg. before sexual activity. The primary outcome was change in baseline to study end in the Clinical Global Impression sexual function scale. Women treated with sildenafil had significantly improved sexual function scores even factoring in women who discontinued the medication prematurely. Baseline endocrine levels were the same in both groups as were depression scale scores. Headache, flushing, and dyspepsia were the most commonly reported side effects of sildenafil. The authors conclude that sildenafil treatment of sexual dysfunction in women taking serotonin reuptake inhibitors was associated with a reduction in adverse sexual side effects (*JAMA.* 2008; 300: 395-404). The study was sponsored by Pfizer, the manufacture of sildenafil.

Electronic Prescribing Worth Your While

If you are not already utilizing electronic prescribing, the government may soon make it worth your while by providing incentive payments to physicians and qualified health care professionals who utilize the technology. Beginning in 2009 Medicare will provide incentive payments for electronic prescribers which will include 2% incentive payments in 2009 and 2010; 1% incentive payment in 2011 and 2012, and a 0.5% incentive payment in 2013. On their website, Health and Human Services states that E-prescribing is more efficient, convenient for consumers, improves the quality of care, and lowers administrative costs. They also suggest that widespread E-prescribing would eliminate thousands of medication errors every year. More information can be found at www.HHS.gov/news/facts/eprescribing.html.

FDA Actions

The FDA has ordered safety-related changes to the labeling of erythropoietin products (Procrit, Ecogen, Aranesp) to reflect safety concerns based on recent data. The new labeling states that the drugs are "not indicated for those receiving myelosuppressive therapy when anticipated outcome is cure." Additionally the agency recommended therapy should not be initiated at hemoglobin levels of 10 g/dL and above, and dosage should be withheld if hemoglobin levels exceed a level needed to avoid transfusion. The FDA also encourages health-care professionals to discuss with their patients the risk of erythropoietin therapy including increased risk of vascular events, shortened time to tumor progression recurrence, and shortened survival.

The FDA has approved the first generic divalproex (Depakote delayed-release tablets) for the treatment of seizures and bipolar disorder, and the management of migraine headaches. Both the brand and generic versions of divalproex carry a Boxed Warning regarding the risk of liver damage and pancreatitis. Eight generic companies have received approval to market divalproex including Upsher-Smith laboratories and TEVA Pharmaceuticals.

The FDA has added a Boxed Warning to fluoroquinolone antibiotics regarding the risk of tendinitis and tendon rupture. The risk is higher in patients older than 60, those taking corticosteroids, and patients with kidney, heart, and lung transplants. Patients experiencing pain, swelling, or inflammation of the tendon or tendon rupture should stop taking their fluoroquinolone immediately and contact their health-care professionals. Fluoroquinolones requiring new labeling include ciprofloxacin (Cipro, Proquin), gemifloxacin (Factive), levofloxacin (Levaquin), moxifloxacin (Avelox), norfloxacin (Noroxin) and ofloxacin (Floxin). ■