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Ventilator-Associated Pneumonia May Not Increase Mortality

ABSTRACT & COMMENTARY

The mortality due to the development of ventilator-associated pneumonia (VAP) in critically ill adult patients has been variously estimated to be between 10% and 50%. Due to the difficulty in precise diagnosis of VAP and the high mortality of patients requiring prolonged mechanical ventilation, the validity and relevance of these estimates remains in doubt. In this study, Bregeon and associates have tried to separate the attributable mortality from VAP by comparing the incidence of VAP in patients who died in the ICU, with case-matched patients who survived. Control cases were matched by diagnosis category, age (within 10 years), sex, date of ICU admission (within 1 year), APACHE II Score (within 7 points), and duration of mechanical ventilation (control at least as long as cases).

Patients were selected from the 475 patients who were not immunocompromised, who required at least 48 hours of mechanical ventilation, and who were admitted to the ICU between 1993 and 1996. Of the 135 consecutive patients who died, 108 could be adequately matched with contemporaneous controls. These pairs served as the study populations. During the study period, VAP was prospectively identified using strict and consistent clinical and bacteriological diagnostic criteria. Treatment with appropriate antibiotics was begun empirically at the completion of cultures and terminated if cultures were not diagnostic. Matching was performed with no knowledge of the presence or absence of VAP. More than 85% of patients were identically matched in all of the selected variables. Groups differed in several important unmatched variables: controls tended to have previously been admitted to another ICU (P = NS), had a slightly lower organ system failure number ($P < .01$), and were less likely to have received steroids prior to ICU admission ($P < .01$). The groups were not different in the frequency of emergency surgery, presence of cancer, requirement for hemofiltration, incidence of the acute respiratory distress syndrome (ARDS), or use of stress ulcer prophylaxis.

The incidence of VAP in the cases was 36.1% compared to an identical percentage of the controls, who received mechanical ventilation for the same duration. When the individual pairs were considered, 23 were concordant (both VAP or both no VAP) and 32 were discordant, half of which were one way or the other. There was no contribution to

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mortality from development of VAP. Multivariate analysis identified only renal failure, bone marrow failure and treatment with steroids, and not the development of VAP, as independent predictors of mortality. The only risk factor identified in this study for developing VAP was the prior use of antibiotics. Other factors such as duration of ventilation, age, APACHE II score, organ system failure score, use of sucralfate, prior steroid treatment, immunosuppressive agents, and the presence of cancer were not apparent risk factors for VAP in this study (Bregeon F, et al. *Anesthesiology*. 2001;94[4]:554-560).

COMMENT BY CHARLES G. DURBIN, Jr., MD, FCCM

There are 2 schools of thought regarding the effect of VAP on outcome of care. The more popular concept is that VAP increases morbidity, cost, and mortality. Most poorly controlled studies show that patients who develop VAP experience a worse outcome than those who do not. This usually includes higher mortality. However, when other risk factors for mortality are controlled, the differences in mortality from VAP are less apparent. This study lends support to the idea that VAP does not actually increase mortality. Its strength is in the success of matching cases with controls. The powerful technique of multivariate analysis suggests that the only independent mortality predictors of death are renal failure, prior use of steroids, and bone marrow failure.

The results of this study should not change the aggressive approach to VAP diagnosis, prevention, and treatment. What was not examined in the study was the effect of the development of VAP on the cost of care. This effect has been adequately delineated in other studies and has been shown to be a large increase in costs due to increased duration of mechanical ventilation and hospital length of stay. This alone justifies the preventive measures suggested.

It should be noted that the diagnosis of VAP is controversial. The criteria used in this study were broad, and the results were unchanged even using different (more or less stringent) definitions. Antibiotic treatment was also aggressive, empiric, and initially resulted in the appropriate choice in more than 75% of cases in both groups.

Caution should be used in applying these conclusions to other patient groups. Very few postsurgical patients were in this study cohort, partly due to the low mortality of surgical as compared to medical patients requiring mechanical ventilation. Cardiac surgery patients, as well as other patients following surgery, may experience increased mortality from VAP, as VAP is a contributor to organ system failure.[1] ❖

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In-Hospital CPR: When to Stop

ABSTRACT & COMMENTARY

Synopsis: *Survival to hospital discharge following in-hospital cardiac arrest and CPR could be predicted with 99% sensitivity using a clinical decision aid that incorporated whether the arrest was witnessed, whether the initial cardiac rhythm was ventricular tachycardia or ventricular fibrillation, and whether a pulse was regained within the first 10 minutes.*

Source: van Walraven C, et al. *JAMA*. 2001;285(12): 1602-1606.

Van walraven and colleagues sought to validate a previously derived clinical decision aid to

reliably predict patients who would have a poor outcome from in-hospital cardiac arrest. They used data from a large registry of in-hospital resuscitation attempts at a community-teaching hospital to determine whether the answers to 3 questions could be used to predict survival to hospital discharge:

1. Was the arrest witnessed?
2. Was the initial cardiac rhythm either ventricular tachycardia or ventricular fibrillation?
3. Was a pulse regained during the first 10 minutes of chest compressions?

If the answer to any one of the above questions was "yes," the patient was classified as having a reasonable likelihood of survival following resuscitation. If none of the questions could be answered in the affirmative, the patient was classified by the decision aid as having no chance for survival.

Data used were from 2181 cardiac resuscitation attempts (in 1884 patients) at the 550-bed hospital from 1987 through 1996. In 15.1% of resuscitations (327/2181), the patient survived to hospital discharge. For 99.1% of these successful resuscitations (324/327), the decision aid would have placed the patient in the favorable prognostic group (95% confidence interval, 97.1-99.8%). Only 3 of 269 patients (1.1%) who were predicted by the decision aid to have no chance of survival did survive to hospital discharge (negative predictive value, 98.9%), and none of these 3 individuals was able to live independently following discharge. van Walraven et al; conclude that this decision aid can be used to help physicians to identify patients who have an extremely small likelihood of benefiting from continued resuscitative efforts.

COMMENT BY DAVID J. PIERSON, MD, FACP, FCCP

A number of factors have been shown to be associated with poor outcomes from attempted resuscitation from in-hospital cardiopulmonary arrest. These include such pre-arrest patient characteristics as hypotension, renal failure, metastatic cancer, pneumonia, and low functional status. Initial cardiac rhythms other than ventricular tachycardia or ventricular fibrillation are associated with unsuccessful resuscitation attempts. In addition, the longer the duration of attempted cardiopulmonary resuscitation, the less the likelihood of patient survival. Previous decision aids based on these and other factors have proven either too cumbersome for quick clinical application or have not been validated in relevant patient populations. This study appears to overcome these problems.

In their discussion, van Walraven et al point out that clinical decision aids should meet several strict methodological standards. These include a clinically important and easily determined outcome (in this case, survival and the ability to live independently) and the requirement that the aid itself be clinically sensible, using components that have been associated with survival in other studies. The latter is met by the present study, since whether an arrest is witnessed, whether ventricular tachycardia or ventricular fibrillation is the initial rhythm, and the duration of resuscitative efforts have all been independently associated with survival in previous studies. In addition, the aid should be validated in a well-defined, appropriately described population.

Use of the simple 3-factor decision aid described in this article could help clinicians to decide when resuscitative efforts should be discontinued after in-hospital cardiac arrest, thus preventing prolonged but ultimately futile resuscitations and the unfruitful use of critical care resources. As van Walraven et al point out, it could also be helpful in discussions with patients about resuscitation in the event of cardiac arrest: For patients who wished not to be subjected to invasive life support without a reasonable likelihood of benefit, the decision aid could be used to assure them that their wishes would be honored. ❖

Special Feature

Does This New Monitoring Gizmo Work?

By David J. Pierson, MD, FACP, FCCP

One day after an operation to remove a large mediastinal tumor, a young man is critically ill in the ICU. The surgery was prolonged and difficult, and massive blood and crystalloid infusions were required. The patient's fluid balance is many liters positive, and he is massively edematous. His chest radiograph shows diffuse bilateral lung opacities, and he requires mechanical ventilation with 100% oxygen and positive end-expiratory pressure (PEEP) to maintain an arterial saturation in the 90s. He is on continuous infusions of norepinephrine to support his blood pressure and vecuronium to maintain therapeutic paralysis. However, although orders have been written for morphine and lorazepam as needed for sedation, he has not received any of either medication for 18 hours because the BIS Monitor® attached to the patient indicates that he is adequately sedated.

Monitoring Sedation by the Numbers

The Bispectral Index® consists of electronically manipulated electroencephalographic (EEG) data from a sensor applied to a patient's forehead and displayed on the BIS Monitor® (Aspect Medical Systems, Natick, Mass) as a number from 0 to 100.[1] A BIS score of 0 is said to correspond to a flat-line EEG, while 100 means that the patient is fully awake; from studies on normal volunteers, a BIS score of 60 indicates deep sedation.[2]

BIS monitoring was introduced in the mid-1990s to eliminate awareness during anesthesia and to facilitate rapid postanesthesia recovery. Its spread from the operating room and postanesthesia recovery unit into the ICU illustrates an often-repeated sequence in the history of critical care: a device or technique developed for a particular setting and tested under one set of conditions is then put into clinical use in managing patients with different problems and under different circumstances. This essay addresses this phenomenon and attempts to provide a framework by which the clinician can judge the appropriateness of using new devices and techniques, particularly those for monitoring critically ill patients, using the BIS Monitor® as a case in point.

Definition of a Critical Care Gizmo

A gizmo, according to the dictionary, is "a gadget, especially a mechanical or electrical device considered to be more complicated than necessary."[3] In the context of this discussion, the definition of "gizmo" may be expanded to include a device or technique in monitoring that is new, used in a new way, or used in a different patient population or clinical setting from that originally intended.

Basically, any device or technique involving technology that has not been clinically validated in the context of its use could be thought of as a gizmo. The entire history of critical care has occurred in only a few decades, and lots of mainstays of today's clinical practice have started out this way: continuous electrocardiographic monitoring, arterial blood pressure monitoring, and pulse oximetry come quickly to mind. However, one could also name many devices and techniques that have come and gone, having been found unnecessary, too complicated, or even harmful after being used on large numbers of patients.

Why Innovation in ICU Monitoring is Needed

Monitoring is central to critical care. It has several purposes, as summarized in Table 1.[4] In attempting to fulfill these purposes and to improve patient care, it is necessary to overcome a number of distinct obstacles. The latter include problems with inaccuracy and imprecision in existing devices, and interindividual variations in reading, interpreting, and transcribing the data they produce. There is the problem of artifact—that is, the signal or result is produced by some mechanism other than the intended one, as with the effect of ambient light on pulse oximeter probes.

Table 1

Purposes of ICU Monitoring

- Assess adequacy of vital organ function
- Track course of patient's illness
- Track effects of therapeutic interventions
- Determine need for specific interventions
- Assess performance of life-support devices and their monitors
- Assess patient discomfort and the effects of efforts to relieve patient distress
- Detect complications and track their severity
- Detect readiness for reduction or withdrawal of interventions

Monitoring is also plagued by factitious data (data the monitor was intended to produce but which does not have the intended implication), as with increased airway pressures generated when a patient coughs. Monitors produce false alarms, accurate measurements signifying real physiologic changes, which are due to physiologic variation rather than to an adverse change in the patient's condition. Some monitors are difficult to use because they are too complex for routine application, despite accurately measuring what they were intended to measure.

All of these things, plus the inherent imperfections and unreliability of mass-produced sensors and other devices, mean that there is presently a substantial gap between concept and reality in ICU monitoring. New monitoring devices or techniques could help in patient management in several ways, but also tend to introduce new problems if they do not deliver as promised (*see Table 2*).

Table 2

Potential Advantages and Disadvantages of a New Monitoring Device or Technique

Advantages

- Capability of assessing something that could not be monitored before
- Capability of assessing something that can already be monitored, but:
  - More accurately
  - Less expensively
  - With less risk or discomfort to the patient
  - More meaningfully

Disadvantages

- Added complexity, cost, or morbidity without gaining practical advantage
- Generation of measurements that are not accurate in this setting
- Generation of measurements that do not mean the same thing in this setting

From Idea to Clinical Practice: Drugs vs. Gizmos

The initial question about whether a given new monitoring gizmo works should really be 4 questions:

1. Does it operate as designed?
2. Does it measure what it is intended to measure?
3. Does the measurement mean what we think it means?
4. Does using the measurement make a difference that is clinically relevant?

While I doubt that anyone would argue with the appropriateness of these questions, answering them requires different amounts of effort and expense. Some types of evaluation are straightforward and not too expensive to do, while others are so onerous as to prevent some potentially worthwhile innovations from being clinically introduced. This is illustrated by comparing the processes by which different kinds of intervention are introduced to clinical practice.

Most clinicians are aware of the process by which a new drug is approved for clinical use. After being identified, chemically characterized, and manufactured in enough quantity to test, the new agent must first be shown not to be unacceptably toxic, usually in studies involving both animals and healthy human volunteers. Once approved for testing on actual patients, it must undergo a series of studies to show that it does have the effect for which it was intended. Small-scale preliminary studies are followed by large-scale (and very expensive) clinical trials to demonstrate clinical efficacy. Only after this extensive several-year (and multimillion-dollar) process is a new drug approved by the Food and Drug Administration (FDA) for clinical marketing and use in ordinary patients.

The process by which a new medical device such as a mechanical ventilator or monitor is approved for clinical use is typically quite different. An all-new kind of device for use on patients must go through rigorous testing (ie, both resource-consuming and prolonged), analogous in some ways to what happens with new drugs under the classification of "Investigational New Device" (IND). In many cases however—especially with ventilators and many monitoring devices—all that is necessary is to demonstrate what is called "substantial equivalence"—the 510(k) process.[5]

If the FDA can be convinced that the proposed new device is just a variation on the basic design of existing (approved) devices—that is, substantially equivalent to them—the approval process is far easier. This is because of the 1976 amendment to the Food, Drug, & Cosmetic Act,[5] which seeks to ensure that new devices do not have to overcome greater regulatory hurdles compared to similar devices that were on the market prior to that time. Companies typically market new devices to the consumer as totally new and different from their competition, but the federal approval process is based on demonstration that they are nearly the same as already-approved devices. Once approved, the new device can be sold to hospitals and used on patients.

The introduction of a new procedure or way of using an existing device (eg, a new surgical procedure or the new lung-protective ventilator strategy for managing the acute respiratory distress syndrome) is different from both of the above. Typically the government is not involved at all. Someone comes up with a new way of doing things, the word spreads, and patients by the dozens, hundreds, and even thousands may be subjected to the new technique. Along the way the promulgator of the innovation and others typically report their experience at scientific meetings and publish clinical series, and if the technique is sufficiently promising or popular, large-scale clinical trials may eventually be performed.

Scientific validation, however, is not part of any federal approval or regulatory process in the case of new techniques and innovative uses of existing technology. However, it should be. This is emphasized by Rubenfeld in a discussion of appropriate study design for assessing new devices and procedures in monitoring: "Intensive care monitoring does not merit clinical use simply on the basis of its making sense; its risks, benefits, and costs, like those of other medical interventions, need to be carefully and empirically demonstrated."[6]

Levels of Testing for ICU Devices and Techniques

Two questions need to be answered before a new monitor is placed in clinical use. Can we do it? And, is it useful? In the approval and introduction sequence just described, wide clinical use sometimes occurs as soon as the first question is answered. A new gizmo is devised, marketed to ICU clinicians, and tried on patients. Only some time later do studies get done to show whether patient care is really made more effective or safer (or less expensive) by the new device.

In its Consensus Conference on Innovation in Mechanical Ventilatory Support, the American Respiratory Care Foundation emphasized the need to match the risks and costs of innovation with the efforts undertaken to demonstrate effectiveness and safety.[7] The scheme proposed for device evaluation by that consensus conference has recently been expanded by MacIntyre[8] and is as appropriate for monitoring gizmos as it is for ventilators. Table 3 lists the levels of evidence proposed by the consensus conference, adapted to inno-

Table 3

Evaluation of a New Monitoring Device or Technique

Level I evaluation
Appropriate setting
- Minor risk to patient; only minor incremental cost increase

Acceptable end points of evaluation: Engineering data
- Measurement accuracy
- Sensor sensitivity or responsiveness
- Noise
- Durability

Level II evaluation
Appropriate settings
- Minor incremental risk to patient; moderate cost increase
- Moderate risk to patient; minor or moderate cost increase

Acceptable end points of evaluation: Physiologic (intermediate end point) data
- Gas exchange; ventilation,
- Airway pressures,
- Respiratory system mechanics,
- Respiratory muscle function,
- Air trapping and auto-PEEP

Level III evaluation
Appropriate settings
- Minor or moderate risk to patient; major cost increase
- Major incremental risk to patient (regardless of cost factors)

Acceptable end points of evaluation: clinical outcomes data
- Survival,
- Days on ventilator; days alive off ventilator
- Length of ICU stay; hospital length of stay
- Incidence of important complications

Adapted from: references (7) and (8).

vations in ICU monitoring, with examples of the kinds of data that are needed at each level.

Does This Particular Monitoring Gizmo Work?

We know from the example of end-tidal CO_2 monitoring and transcutaneous arterial blood gas monitoring that systems validated in healthy people under carefully controlled circumstances do not always work out as well in the uncontrolled environment of the ICU and in unstable, critically ill patients. This brings us back to BIS monitoring. Several aspects of the patient scenario with which I began this essay are different from the setting for which the BIS Monitor® was originally introduced. What is the meaning of the processed EEG signal and its derived index in critically ill patients with different underlying diseases? How do hemodynamic instability, severe hypoxemia, PEEP, and multiple organ failure affect the measurement and its interpretation? What are the local effects of vasoconstrictor drugs or soft-tissue edema at the sensor site? How well do the sensor and other aspects of the system stand up to frequent patient turning and other manipulation in the sometimes frenetic critical care environment?

At its web site, the manufacturer promotes use of the BIS Monitor® in the ICU, stating that "BIS provides an objective tool for assessing level of sedation in critically ill patients. "[It] may be especially useful for assessing sedation in patients with neuromuscular blockade [and] mechanical ventilation. . ."[9] To what extent has BIS monitoring been studied in the ICU setting, and what do the available data say about whether we should adopt this new gizmo in managing our patients?

A June 4, 2001, MEDLINE search on "Bispectral index" yielded 171 citations, but only 2 of them were full papers reporting clinical trials in ICU patients.[10,11] Two additional studies were presented in poster form within the last 6 months, at the annual conventions of the Society of Critical Care Medicine[12] and the American Thoracic Society.[13]

In the first published investigation of BIS monitoring in the ICU, De Deyne and colleagues in Belgium studied 18 deeply sedated surgical ICU patients, all of whom were unresponsive to bedside stimulation and deeply sedated according to the clinical Ramsay Sedation Score (RSS).[10] The BIS score was below 60, indicating deep sedation, in 15 of the 18 patients, but the scores varied widely. De Deyne et al concluded that more extensive study was needed.

Simmons and associates at Maine Medical Center evaluated multiple assessments of sedation in 63 sedated, ventilated adult ICU patients.[11] A single, trained observer blinded to the bispectral index prospectively evaluated the clinical level of sedation using the revised Sedation-Agitation Scale (SAS). Sedation levels varied widely, from very deep sedation (SAS 1, BIS 43) to mild agitation (SAS 5, BIS 100). The average BIS score correlated statistically with the average SAS score ($r^2 = 0.21$; $P < 0.001$). However, the correlation between the two varied in medical, surgical, and trauma patients, and De Deyne et al concluded that further research was necessary to define the role of BIS monitoring in the ICU.

Nelson and associates from Honolulu recently presented results from a prospective study of 26 intubated, ventilated medical ICU patients.[12] Nelson et al made simultaneous assessments of sedation using BIS, the Spectral Edge Frequency (SEF, a second computer-derived EEG parameter), the RSS, the Modified Observer Assessment of Alertness and Sedation Scale (MOASS), and the Glasgow Coma Scale (GSS). A blinded observer made all the clinical assessments. A total of 176 separate sets of assessments were made. Although statistically significant, the correlation between GCS and MOASS and BIS or SEF was not very strong, and the BIS or SEF scores could not be determined using the other tests. Disturbingly, some low

BIS scores were obtained in patients who were awake, and high BIS scores in patients who were unarousable. In 17 readings, the BIS and SEF scores decreased when the patient was stimulated. Nelson et al concluded that, in their MICU patients, the bedside EEG monitor and BIS or SEF scores could not be used in lieu of clinical assessment of the level of sedation.

The most recent study was presented in May by de Wit and colleagues from Boston.[13] They reported on simultaneous comparisons of BIS and SAS scores in 19 medical ICU patients, in whom 60 sets of measurements were made before and after stimulation. SAS scores ranged from 1 to 5, and BIS scores ranged from 32 to 98. Although a statistical correlation was obtained between the two assessments (r^2 = 0.47 and 0.43 before and after stimulation, respectively), BIS varied widely for a given SAS. For SAS = 1, BIS scores ranged from 32-96; for 2, 36-98; for 3, 74-98; for 4, 75-98; and for 5, 89-97. de Wit et al concluded that, although SAS correlated with the level of awareness as assessed by BIS, at lower SAS scores the range of BIS scores was wide.

These last two studies have not yet appeared as full papers, and still need to be subjected to full peer review. Thus, the available database on BIS monitoring of critically ill patients in the ICU setting is pretty limited. In a 1999 editorial accompanying publication of the Simmons study previously cited, Shapiro stated, "More investigations are needed to determine the reliability of the BIS in the ICU and how we should use it to provide optimal sedation/analgesia."[14] This remains the case.

Unfortunately, the definitive study establishing the role of BIS monitoring may not soon be forthcoming. In a recent power- and cost-analysis of what would be required to demonstrate whether BIS monitoring prevents awareness during general anesthesia, O'Connor and associates estimated that a study of as many as 800,000 patients might be required, depending on the frequency of the event in question.[15] They calculated that the cost to prevent a single case of awareness during anesthesia could be as high as $400,000, although it could also be much less. O'Connor et al point out that there are reported cases of awareness during anesthesia despite BIS values indicating adequate sedation.[15] Based on the available data from observations in the ICU, the frequency of this complication could be considerably higher there.

Conclusion

Innovations in ICU monitoring—new gizmos—typically reach clinical introduction and become part of routine patient care with less rigorous testing than occurs with new pharmacologic agents, particularly with respect to the clinical usefulness of the data generated. The management of critically ill patients has been greatly aided by some of these gizmos, although others have added only complexity and expense and a few have been clinically harmful. Because of the manner in which new monitoring technology and approaches reaches the bedside, it is up to the clinician to maintain objectivity and a degree of skepticism until the real value of a particular gizmo has been demonstrated.

Monitoring sedation in critically ill patients, particularly in the face of neuromuscular blockade, is an extremely important activity presently guided by cumbersome and imprecise tools. This is definitely an aspect of critical care that is in need of innovation. The BIS monitor has been embraced by many anesthesiologists as a convenient, quantitative aid in the prevention of awareness during anesthesia and to hasten postanesthesia awakening. The possibility that this new gizmo might also be helpful in guiding sedation in critically ill ICU patients is exciting and should stimulate wider investigation. For now, however, it is experimental in the ICU, and I would be hesitant to use it outside the investigational setting, particularly as the sole assessment of a patient's level of sedation. ❖

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CME/CE Questions

16. In case-matched pairs, when survivors are compared to patients who die:
a. the frequency of steroid use is higher.
b. the presence of prior antibiotic use is higher.
c. the incidence of VAP is the same.
d. organ system failure is the same.
e. no effect of duration of ventilation on VAP incidence is seen.

17. Since the incidence of VAP is identical in survivors and patients who die who were ventilated for the same duration:
a. antibiotic treatment of VAP is unnecessary.
b. all patients should be extubated as soon as possible.
c. VAP should only be treated aggressively in the sickest patients.
d. pressure support ventilation should be used in all patients.
e. inhaled prophylactic antibiotics are indicated after 48 hours.

18. Using a clinical decision aid that incorporates the circumstances and initial electrocardiographic rhythm plus the success of the first 10 minutes of CPR, how often would CPR have been stopped inappropriately in patients who would have survived to hospital discharge?
a. Never
b. In about 1% of patients
c. In about 5% of patients
d. In about 15% of patients
e. In nearly one-half of the patients

19. A clinical decision aid to guide the discontinuance of CPR in hospitalized patients had a sensitivity of approximately 99% in predicting survival. It incorporated the initial cardiac rhythm, whether the arrest was witnessed, and which of the following?
a. The hospital service (eg, medicine or surgery) to which the patient was admitted
b. How quickly CPR was begun
c. Whether the patient had an underlying malignancy or degenerative disease
d. Whether a palpable pulse was regained within the first 10 minutes of CPR
e. The patient's age (younger than 70 vs older than 70 years)

20. Which of the following statements about using the bispectral index (BIS) to monitor the adequacy of sedation in paralyzed, ventilated medical ICU patients is true?
a. It eliminates the need for clinical assessments of sedation level.
b. It consistently underestimates the level of sedation as determined by clinical assessment.
c. It consistently overestimates the level of sedation as determined by clinical assessment.
d. Its results are less reliable in this setting than in the operating room.
e. None of the above

21. Most new medical devices are approved for marketing:
a. by a process virtually identical to that for new drugs.
b. through a rigorous process of evaluating an all-new type of device.
c. by demonstration that they are substantially equivalent to existing devices.
d. without submission to any governmental agency.
e. only after months or years of clinical use.

22. According to the American Respiratory Care Foundation's scheme for evaluating ICU innovations, which of the following end points would be appropriate in a study of monitoring the adequacy of sedation in paralyzed, ventilated patients?
a. Gas exchange
b. Signal transmission from remote sensor
c. Sensor sensitivity and responsiveness
d. Incidence of post-traumatic stress disorder
e. Oxygen consumption

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:

Percutaneous vs. Surgical Tracheostomy

CRITICAL CARE Plus

EXPANDING YOUR FOCUS IN INTENSIVE CARE

Trauma Workers Disregard Exposure Risks

New methods needed for precaution compliance

By Julie Crawshaw

Universal hospital mandates haven't caused trauma health care workers to comply with universal barrier precautions, a new study from Louisiana shows. A research team headed by Atul Madan, MD, chief surgical resident at the department of surgery at the Tulane University School of Medicine observed both physicians and nursing staff resuscitating patients at Charity Hospital. They found compliance rates for individual-barrier protection in 104 health care workers were: gloves, 98%; eyewear (any type), 52%; gowns, 38%; masks, 10%; and eyewear (with side protectors), 9%.

Only two of 59 health care workers attending bleeding patients used full-barrier protections, for an overall compliance rate of only 38%. No difference in compliance rates occurred during the study period.[1]

Madan's team found that many of their fellow physicians and nursing staff members were nonchalant about using appropriate universal precautions when they resuscitated trauma patients. The level of physician or staff member experience did not affect their rate of barrier precaution compliance. Physicians wore eye protection more often than did the nursing staff but still had poor overall barrier-protection compliance.

"We believe our data have serious implications for urban trauma centers," Madan says. "We know that many [health care workers] simultaneously underestimate the risk of blood-borne pathogens and overestimate their compliance with appropriate protections."

Barrier precautions were considered properly used if worn at all times when the workers were in direct contact with a patient. Researchers recorded times and types of all observed procedures, the presence or absence of obvious external hemorrhage, the type of staff (nursing staff vs. physician), and whether the worker arrived before or after the patient did.

A fourth-year medical student observer (unknown to any health care workers) recorded compliance with four protections: gloves, masks, gowns, and eyewear. Eyewear was divided into those types with and without side protection.

Only those workers who were in direct contact with a patient were included in this study, and no health care worker had any knowledge that he was being observed. The medical student stood on an observation platform often used by other medical students.

The "It Can't Happen To Me" Syndrome at Work

Though Madan believes a certain amount of precautionary deficit is institutional-dependent, he says if you look at all of the available data, compliance rates are poor overall. "I think it's partly kind of a cavalier attitude," Madan says. "People think 'It's not going to happen to me.' " He says that in the operating room, everyone is trained to use appropriate universal precautions. "You wouldn't think of entering an OR without gown, mask, and gloves. But in trauma resuscitations, the urgency people feel gets in the way," he says. "Ironically, when physicians have to protect the patient more than themselves, they seem to be more compliant."

A previous study of which Madan was also the lead author[2] showed that the number of HIV-positive trauma patients is significantly higher than in the general population. "In patients suffering from penetrating traumas like bullet and knife wounds, the HIV-positive rate was eight times higher than in the general population," Madan says. "Moreover, most of the health care workers attending these cases—often without sufficient barrier precautions—did not know their patients were HIV-positive."

Madan is more concerned about hepatitis C transmission as a blood-borne disease. "It's a lot more prevalent than HIV and there's no vaccine like there is for Hepatitis B," he says.

This study reported evidence of external hemorrhage as the only factor predictive of barrier protection compliance, but visible blood was associated with mixed changes. Researchers found higher rates of eyewear compliance when patients were visibly bleeding, but gown compliance for these cases was actually lower. That may be because penetrating trauma wounds have more external bleeding than do wounds from blunt traumas and thus afford a greater opportunity for the patient's blood to wind up on the health care worker.

Recent research[3] reports nosocomial bloodstream infections are a leading cause of death in the United States. However, Madan sees blood-borne pathogen transmission from health care worker to patient as less likely in trauma units than in ICUs.

Third Study Now in Progress

Madan's team is currently researching other reasons health care workers aren't using universal precautions. He points out that at a large trauma center, where 15-20 resuscitations are performed every day, the process becomes routine. "Unless barrier precautions are equally routine, it's very easy to ignore them," he says.

Once the current study is completed, Madan anticipates looking for ways to change the status quo. "The final piece will be determining how we can encourage using barrier precautions all the time," he says.

David E. Rentz, MD, MPH, an emergency medicine physician at Louisiana State University's Charity Hospital, participated in the noncompliance study. He calls the lack of universal precaution compliance an excellent example of what happens when people become desensitized to high-risk behaviors associated with tasks they perform repeatedly.

"When you take risks but don't see any ramifications, you become desensitized to the possibility of blood-borne pathogen transmissions," he says. He points out that a health care worker racing into trauma resuscitation may simply not take the 20 seconds needed to put on a face mask or protective eyewear. "When the patient is bleeding many of us just accept the risk unless the blood is squirting us in the face," Rentz says.

Rentz believes that changing precaution-compliance behavior will take more than education. "Education goes on all the time," he says. "It may require a crisis before people change." ❖

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Pediatric End-of-Life Improvements Sought

IOM committee begins deliberations

A new institute of medicine (iom) committee is looking for ways to ameliorate end-of-life care services for dying children that include possible revisions of the current federal reimbursement regulations.

"The whole problem of reimbursing for children who are in the dying phase of their disease or need palliative care is a real issue," says committee chairman Richard E. Behrman, MD, JD. Reimbursement is only one item on the panel's agenda, says Behrman, senior vice president for medical affairs at the Lucile Packard Foundation for Children's Health, and a clinical professor of pediatrics at Stanford University and the University of California-San Francisco.

The project, called Challenges of Providing End-of-Life Care for Children and Families, will look at all the factors that influence pediatric end-of-life care. "Our objective is to provide a comprehensive look at what we know and don't know about care for dying children, and what we know about good care that we don't use," says Marilyn Field, PhD, senior IOM program officer and study director for the project.

The committee isn't making an explicit point-by-point comparison between end-of-life care for children and adults but will explore certain parallels. "We're very interested in getting the attention of the critical care community," Field says.

Field says the committee will investigate the extent to which children are admitted to ICUs with a prognosis that death is virtually certain. "We're also looking at the kinds of communication that happen with parents, and when the physician and parents understand that survival isn't expected," she says.

Though accidents are the most common cause of pediatric death, many deaths from injuries bring children into pediatric critical care units. "The situation appears to be that prognosis for children is often more difficult," Field says. "Their physiology is different, they're more resilient, the major causes of death are different so it appears they are not as likely to fit the hospice care definition used by Medicare."

Field observes that the HCFA "six-months-before-death" rule for hospice eligibility that allows reimbursement for palliative care is extremely difficult for critical care physicians to apply. Because predicting life duration is tricky for any patient, even the elderly, many older patients are unable to benefit from hospice-type services.

"When the patient is a child the situation becomes more complicated," Field says, "because parents are often unwilling to completely forego curative or life-extending care, which is a reimbursement condition in most Medicaid programs."

The study group aims to develop recommendations for increasing compassionate and effective care for dying children and their families. It is sponsored by the National Institute of Nursing Research, the Ryan White Program of the Health Resources and Services Administration (US Department of Health and Human Services), and the Open Society Institute.

As presently defined, the committee's charges include:

- Describing the major causes of death for children, site of death, and differences in the dying process for different causes of death;
- Assessing the state of knowledge about clinical, behavioral, cultural, organizational, legal, and other important aspects of end-of-life care for children and their families;
- Considering methods for measuring care outcomes, determining family and child/patient preferences, communicating information, resolving conflicts, and assessing end-of-life care as experienced by children and their families;
- Examining the availability, evidence base, and usefulness of practice guidelines for clinicians who care for dying children;
- Proposing a research and action agenda to strengthen the scope and application of the knowledge base for providing effective and compassionate care for dying children and their families.

Committee plans include a public meeting scheduled for September. "We expect to invite testimony and statements of views from interested organizations," Field says. Written statements from individuals may not receive committee responses due to staff and time constraints but can be submitted to the Challenges of Providing End-of-Life Care for Children and Families Project, 2101 Constitution Avenue NW, Washington, DC 20418. Telephone: (202) 334-2310. ❖

Don't Let Your ICU Computer Bug You

Checking out system avoids health and financial costs

Computers installed to help streamline icu procedures at Mclaren Regional Medical Center brought more infections in their wake. Mclaren ICU physician Gregory Forstall, MD, diagnosed a patient with *Aspergillus fumigatus*, an infection rarely found at the Flint, Mich, facility, shortly after the new electronics were installed.

The computers had vents with exhaust-producing cooling fans, Forstall reported at a recent meeting of the American Society for Microbiology. When he and his colleagues cultured dust samples taken from the computer vent and from room air about 6 ft away, they found several types of yeast and some filamentous mold. Forstall's group identified isolates of *Candida*, *Aspergillus niger*, *Phaeoannellomyces*, *Rhodotorula*, and *Rhizopus*. They concluded that ICU infection-control measures should include routine cleaning of computer vents.

Is the Benefit Worth the Cost?

Mold and yeast may not be the only ICU computer problem. At least one study shows that spending scarce dollars on expensive state-of-the-art computerized equipment does little to improve ICU patient outcomes.[1]

More than half the ICUs in the United States are reportedly interested in acquiring physiologic trend-monitoring equipment, which provide real time data about the patient's heart and respiratory rates, blood pressure, and chest drain levels by displaying continuously updated readings on a computer screen.[1]

However, a randomized controlled trial of the system

was unable to show much patient benefit. A group of clinical researchers reported initially that the system could alert ICU staff to sudden changes in patient condition sooner than conventional systems. The research team established a working hypothesis that the system's monitoring efficiency would more than justify its high cost. But when they tested this theory they found the system failed to ameliorate results.

Moreover, research done by Jon N. Meliones, MD, found that presenting data via physiologic trend systems "does not significantly add to the daily management of patients."[2] Meliones, who heads the pediatric critical care staff at Duke University Medical Center in Durham, NC, says that ICU staff members constantly monitor and interpret patients vital data regardless of whether the information is presented in tabular or computerized form. ❖

References

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New Staffing Report Claims Nursing Shortages Worse

PA group offers solutions

The hospital & healthsystem association of Pennsylvania (HAP) recently issued a report that predicts the state's current registered nursing shortage will worsen before it improves. The report collates information about the current nursing workforce with figures for nursing school enrollments and graduates, health care financing, and patient demographics.

Carolyn F. Scanlan, HAP president and CEO, says the findings illustrate the problems faced by health care providers and consumers alike. "All of the demographic trends are going in the wrong direction, and these trends now appear to be long-term rather than cyclical," Scanlan says.

The report found that the adverse effects of the shortage of nurses are exacerbated by the "shaky financial condition of Pennsylvania's hospitals and a broader range of job opportunities for all workers." Current trends project a nationwide shortage of more than 400,000 nurses by the year 2020.

To deal with nursing shortages in Pennsylvania, HAP recommends:

- Adequate funding for health care, meaning government and private payers must fairly reimburse hospitals so they can offer competitive salaries to health care workers and invest in technology and systems that will improve patient and worker safety;
- "Cost of caring" payment adjustments from Medicaid, Medicare, and private payers that provide money to staff at adequate levels;
- Increased financial support for nursing and allied health education from government and private payers to prevent further nursing school closures;
- Financial incentives for students through loan forgiveness and scholarship programs;
- Comprehensive collection and analysis of health care work force data by the Pennsylvania Department of Labor and Industry;
- Continued improvements in the delivery of patient care;
- Flexibility in facility and professional licensure requirements so nurses can effectively provide and coordinate patient care and to practice to their fullest potential;
- Examining facility and professional licensure requirements for their effect on improvement and patient safety;
- Nursing career outreach through education programs that promote nursing and health care careers performed in collaboration with health care delivery;
- Partnership between health care delivery systems and nursing education programs that strengthen continuing education and professional development in the current nursing workforce;

An Adobe "PDF" version of "Pennsylvania Nurses: Meeting the Demand for Nursing Care in the 21st Century" is available for download by clicking on "workforce" at www.haponline.org/hhap (Accessed June 11, 2001). ❖

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Readers are Invited. . .

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