Quality and the Future
By Al Minjock, RN, MSN; Director: Clinical and Economic Services, Edwards Lifesciences

Cost, quality and accessibility seem to be the mantra of healthcare delivery in the United States in 2008. Healthcare organizations struggle to combat the ever-changing world of reimbursements as they get further and further inter-twined with quality measures.

This has never become more evident as with the “Value-Based Purchasing Program” outlined by the Center for Medicare Services (CMS) in November of 2007. The goal of this system is to help lower the cost of healthcare through the achievement of quality indicators that will ensure implementation of current standards of care. While this concept presents interesting opportunities for various stakeholders, it has yet to be proven that it will actually achieve the desired results.

“Pay for Performance” Revisited
The CMS proposal is very similar to “pay for performance,” which has become very familiar to most providers over the past decade. Such a value-based program would recommend severe financial penalties for those facilities that fail to achieve the requested performance markers while offering no financial incentive for success other

HEMODYNAMIC MONITORING UPDATE
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Current trends in hemodynamic monitoring are
(1) the movement away from invasive monitoring towards less-invasive or non-invasive methods of monitoring,
(2) moving away from resuscitation solely based on standard endpoints (e.g., normalization of heart rate, blood pressure, cardiac output) and toward indicators that are based on optimizing tissue oxygenation (e.g., SvO₂, ScvO₂, lactate), and
(3) the integration of these data into evidence-based resuscitation protocols and not solely as stand-alone markers.

Since the mid-1990s there has been a decrease in the use of pulmonary artery (PA) catheters. This trend is related to a number of studies that suggested there was no significant improvement in patient outcomes associated with use of the PA catheter. These studies left more questions than answers. For example, was the lack of benefit because providers were not using the hemodynamic data correctly? Was it because the PA catheter was used only as a monitoring device versus a device linked to a protocol that has been shown to improve patient outcomes? Or was it because the data being used, such as the PAOP and CVP, did not allow us to answer the right question?

Key Areas of Research
First-line therapy in resuscitation of critically ill patients is generally the administration of fluids. At the bedside we are challenged by this question: If a patient is hypoperfused, will the administration of a fluid bolus improve stroke volume and thus the delivery of oxygen to the tissues? Research has repeatedly shown that our standard methods of measuring a patient’s preload (CVP and PAOP) do not predict if the patient will respond to a fluid bolus. In fact, only 50% of patients will respond to a fluid bolus with an increase in stroke volume.

“Only 50% of patients will respond to a fluid bolus with an increase in stroke volume.”

Recent research has demonstrated that the use of dynamic indicators – systolic pressure variation, pulse pressure variation and stroke volume variation, which provide insight into the function of the patient’s heart – are more sensitive and specific indicators of fluid responsiveness. One exciting thing about these indicators is that they can be obtained from the arterial line, and there is ongoing research to determine if similar types of indicators can be obtained from a pulse oximeter.
The third annual grant for research on nurse-driven clinical practice outcomes was awarded to Dai Wai Olson of Duke University, Durham, NC, during the National Training Institute at the May meeting of the American Association of Critical-Care Nurses (AACN). The grant is co-sponsored by AACN and Edwards Lifesciences.

Edwards Lifesciences’ credo in part is to become trusted partners in order to provide the best care to help patients, especially those with cardiovascular disease. We have a long history of supporting the American Association of Critical-Care Nurses with grants for research, educational material, and sponsorship of speakers and programs. In 2006 we began our most recent collaboration with AACN by co-sponsoring one of the large AACN Grant Awards. The focus of the grant is to evaluate protocol-based care driven by critical care nurses as they become empowered to make their optimal contribution to the care of the critically ill and their families.

Grants, which can total up to $6,500 each, are intended to fund research relating to the use of protocol-based care driven by nurses. Recipients must have research experience and must agree to disseminate the research results in a timely manner. According to AACN, the research should address these issues as they relate to acute or critically ill individuals:

1. To what extent are nurses engaged in nurse-driven protocol-based care?
2. How successful are nurses in doing so?
3. How do nurses’ outcomes compare to protocols driven by other healthcare professionals?

The application reviewers are particularly interested in research that focuses on the following at any point in the continuum of acute or critical care:

1. Implementation of nurse-driven protocols using technology, including minimally invasive devices, with evaluation of patient outcomes and nurses’ roles in implementing the protocols.

Further information and application materials are available on the AACN web site, Large Grant Program [http://aacn.org/AACN/research.nsf/vwdoc/grantSupport]. The application deadline is October 1.
PediaSat Pediatric Oximetry Catheter Tested in Cardiac Surgery Patients

Cardiothoracic surgeons and anesthesiologists at the UCLA medical school evaluated a new central venous oximetry catheter for central venous oxygen saturation (S\textsubscript{c\textsubscript{v\textsubscript{O}_2}) monitoring in pediatric patients undergoing cardiac surgery. This catheter (PediaSat oximetry catheter, Edwards Lifesciences) features an integrated fiberoptic oximeter within a standard multi-lumen central line. It was designed to provide central access, measure pressure, and monitor S\textsubscript{c\textsubscript{v\textsubscript{O}_2} continuously in critically ill children.

This report describes both animal and clinical research undertaken to evaluate the catheter. In animals, the accuracy of this S\textsubscript{c\textsubscript{v\textsubscript{O}_2} catheter was compared to ScvO\textsubscript{2}, blood co-oximetry, and its correlation to cardiac index (CI) and systemic hemodynamic variables was documented. The catheter was then evaluated in 16 pediatric patients undergoing cardiac surgery, and its accuracy and reliability were assessed.

The investigators reported the following.

In the animal study:

- Close correlation between saturations obtained from the fiberoptic S\textsubscript{c\textsubscript{v\textsubscript{O}_2} catheter and blood gas co-oximetry during controlled changes in CI and hemodynamics (r≈0.94).
- Bland-Altman analysis revealed a low bias (+0.03%), indicating the absence of any systematic errors between the two methods, and a ± 4.41 precision.

In the pediatric surgical patients:

- A close relationship between the catheter’s ScvO\textsubscript{2} readings and CI; ScvO\textsubscript{2} correlated better to CI than the more commonly used hemodynamic variables in children (HR, MAP, MPAP, CVP).
- Changes in S\textsubscript{c\textsubscript{v\textsubscript{O}_2} reflected acute alterations of cardiovascular status secondary to the surgical or anesthetic interventions during the case.

Further, the catheter was safely placed percutaneously in small patients (smallest was 4.2 kg), with no catheter-related complications.

They concluded that this catheter provides a “...less invasive, safe and accurate method for perioperative continuous ScvO\textsubscript{2} monitoring in this high-risk patient population.” They pointed out that integrating continuous ScvO\textsubscript{2} fiberoptic oximetry catheters into small pediatric central venous catheters overcomes the limitations of conventional methods which are limited by patient size and require additional invasive procedures.


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than the ability to continue to operate. As Karen Wolk Feinstein, CEO of the Jewish Healthcare Foundation in Pittsburgh, PA, commented: “There have been a number of efforts in recent years to create ‘pay for performance’ systems that add new rewards or incentives to existing healthcare payment systems in order to encourage lower-cost, higher-quality health care. But that’s not enough. There is a growing consensus that in order to achieve the most efficient, effective, and sustainable improvements in quality and reductions (or slowing the growth) in costs, the penalties and disincentives in the underlying healthcare payment system must also be eliminated or modified.”*

Third-party payers have also begun to understand the need to drive care and decrease costs through effective and evidenced-based standards. Insurance companies in Michigan, California, Texas, and several New England states now require the reporting of the incidence of several hospital-acquired conditions including surgical site infections, urinary catheter related sepsis, and critical care specific conditions. Healthcare organizations are then provided significant financial incentive to reduce the rate of these conditions. Not to be left out, CMS announced that they would begin to withhold repayment for costs associated with certain “hospital acquired illnesses.” It appears that healthcare organizations are attempting to respond by increasing surveillance and developing elaborate monitoring services – all of which are aimed at holding reimbursement at current levels, not attracting new or incrementally increased payments.

All is not lost. There certainly exist ways in which healthcare organizations and practitioners can help shape their destiny. One of these involves the identification and management of the septic patient. An extensive body of evidence has shown that patients presenting with the signs and symptoms of systemic inflammatory response syndrome (SIRS) can be reasonably and easily treated, leading to significant cost reductions. These “sepsis bundles” encouraged by the Institute for Healthcare Improvement (IHI) are readily available in various forms and can be implemented in a variety of methods to achieve the desired outcomes. It is interesting to note that these IHI markers are currently being considered for national reporting by the Hospital Quality Alliance as well as the National Quality Forum.

While it is certain that we are all under pressure from all fronts, as healthcare providers we should consider this an opportunity to utilize evidenced-based research that is readily available to drive the best possible care for each and every patient with whom we come in contact.

Additional information:

- Institute for Health Care Improvement Website (www.IHI.org).

Two of the principal themes of the presentations at the SCCM 37th Critical Care Congress held in Honolulu in February were sepsis and glucose monitoring and control. Following are brief summaries of reports on these and other topics that may be of interest.

### SEPSIS

#### Severe Sepsis Dx Frequently Missed in ICU

A large survey in Maryland found that, while 4.8% of 25,582 ICU patients met the physiologic criteria for a diagnosis of severe sepsis (SS), only 2.2% had been diagnosed. Among those diagnosed, 74% had cardiovascular organ dysfunction/shock. The undiagnosed patients had a wider variety of organ dysfunctions (OD): 53% neurologic, 22% respiratory, and 15% lactic acidosis, with 37% listed as CV/shock. The authors suggest that clinicians may be missing severe shock by focusing on CV conditions. They said, “Associating other ODs with SS would increase reporting, potentially leading to improved treatment, reimbursement and severity scoring.”

Badawi O, Holl R, Hassan E, et al. Severe sepsis is underreported in the ICU. Abstract #918.

#### “Sepsis Nurse” Enhances Patient Care

The University of Texas Hospital trained “sepsis nurses” to identify and follow inpatients who were at high risk for developing sepsis. Candidates were patients with central lines, diabetes, liver or kidney disease, leukocytosis, neutropenia, or those with an obvious source of infection. Such patients were monitored daily, and both the attending physician and rapid response team (RRT) were contacted if there was cause for concern. In the two years after the sepsis nurse was added, the number of calls to the RRT increased from an average of 31/month to 78/month (p=0.0001), while the number of codes decreased from 1.59/month to 1.24/month (p=0.27). The researchers concluded that the increased number of calls indicates that high-risk patients were brought to the attention of the RRT earlier, correlating with a “possible trend” toward fewer codes.


#### Sepsis Initiative Improves Clinical and Financial Outcomes

A 698-bed teaching hospital in Houston, TX, implemented an initiative consisting of a sepsis protocol and education of hospitalists, ED physicians, medical residents, and nurses on early screening and the sepsis treatment bundle. Retrospective analysis of data from the 15-month period before the initiative compared with data in the 15 months after the initiative revealed:

- Mortality decreased from 28.2% to 22.1% (p=0.0002)
- Time on a ventilator dropped from 7.2 to 5.6 days (p=0.0008)
- Total length of stay declined from 19.2 to 17.7 days (p=0.022)
- ICU length of stay decreased from 10.8 to 9.7 days (p=0.027)
- The total cost of treatment per case was reduced from $53,342 to $48,535 (p=0.0464). Thus, the authors concluded, “A multi-faceted sepsis initiative improved clinical outcomes and substantially reduced cost of care.”


### GLUCOSE LEVELS

#### Glucose Levels Highly Variable in Sepsis Patients

At the Cardinal Health System in Marlborough, MA, researchers determined that only 24% of 8,389 sepsis patients admitted to 64 hospitals had glucose levels controlled in the 81-130 mg/dl range. Measures taken within the first two days of hospitalization revealed this range of uncontrolled glucose levels:

- 42% had hyperglycemia
- 17% had severe hyperglycemia (>230 mg/dl)
13% had hypoglycemia
4% had severe hypoglycemia (<51 mg/dl)

Overall crude mortality was 17.8%. Risk adjusted mortality odds ratios were 3.09 for patients with severe hypoglycemia and 1.70 for those with severe hyperglycemia. The odds ratios were 1.52 and 1.15 for hypo- and hyperglycemia, respectively. The researchers analyzed the cost burden and determined that the risk adjusted excess cost for patients with glucose variability ranged from $900 to $3800, compared with patients with controlled glucose.


Nursing Protocol Improves Glucose Control

The importance of empowering the nursing staff was demonstrated in a study in the trauma ICU at the Los Angeles County/University of Southern California Hospital in Los Angeles, CA. A new protocol for tight glycemic control, which was developed with input from the nursing staff, shifted much of the responsibility for insulin administration to the bedside nurse. Three months after the protocol was implemented, the mean blood glucose levels achieved had improved from 137.7 mg/dl to 125.4 mg/dl. Time to achieving glucose goal improved from 37 hours to 8 hours.


MINIMALLY INVASIVE MONITORING

New FloTrac Indicator Flags Extreme Hyperdynamic Periods

It has been suggested that arterial pressure cardiac output (APCO) monitors may underestimate cardiac output (CO) in patients with severe sepsis who are in a hyperdynamic state (high CO, loss of vascular tone). This study was done to determine whether arterial waveform analysis can serve as a reliable indicator of the potential for this underestimation of CO by APCO monitors as compared with PAC monitoring.

Analysis of 109,500 data points from 6 patients in the study yielded specificity and sensitivity calculations of 0.9 for both. Thus, the authors said, “The new FloTrac indicator [Edwards Lifesciences] reliably identified the periods of extreme vasomotor instability during which APCO underestimated cardiac output as compared to CCO.” They suggested future research to evaluate the prognostic significance of this finding.


New AHA Statement Calls for Glucose Monitoring of ACS Patients

Hyperglycemia is common among patients hospitalized with acute coronary syndrome (ACS) and is also associated with “markedly increased” mortality rates in these patients. The American Heart Association (AHA) recently issued a Scientific Statement outlining the current state of knowledge about this subject and identifying the most important knowledge gaps in the field. These gaps included:

- Developing optimal ways of measuring and monitoring glucose values during hospitalization for ACS.
- Better understanding of the physiological mechanisms responsible for poor outcomes associated with hyperglycemia.
- Agreeing on a specific definition of hyperglycemia.
- Determining whether elevated glucose is a direct mediator of adverse outcomes in ACS patients or just a marker of greater disease severity.

The statement cites research that showed a 13% to 77% relative increase in 30-day mortality and a 7% to 46% relative increase in one-year mortality, depending on the degree of hyperglycemia, among hyperglycemic patients hospitalized with ACS.

While more research is needed to elucidate answers that will enable formal guidelines, the AHA made several recommendations, including that glucose levels should be obtained upon admission and closely monitored in patients with ACS who are admitted to an ICU.


PLEASE JOIN US AT THESE CONFERENCES

Learn more about less invasive hemodynamic monitoring, fluid management, and other critical care topics by visiting the Edwards Lifesciences booth at any of the following events.

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<tr>
<th>Dates</th>
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<tr>
<td>May 6-8</td>
<td>AACN National Training Institute and Critical Care Expo, Booth#2413</td>
<td>Chicago</td>
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<tr>
<td>August 9-13</td>
<td>American Association of Nurse Anesthetists (AANA), Booth #902</td>
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<td>Sept. 24-27</td>
<td>Emergency Nurses Association (ENA), Booth #1307</td>
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There are still numerous areas for research regarding these dynamic indices, such as:

- how to measure them in spontaneously breathing patients or individuals with arrhythmias,
- the effect of low tidal volume ventilation on the thresholds in predicting a patient’s fluid responsiveness, and
- their use in patients with decreased ejection fractions.

The challenge now is to integrate these indicators into treatment algorithms to allow us to further tailor a patient’s therapy. For example, rather than solely aiming for a CVP of 8 mm Hg as an indicator of the adequacy of volume resuscitation, using these dynamic indices may enable us to more accurately identify a patient who will no longer respond to fluids despite a relatively low CVP; thus, we can more carefully tailor their fluid resuscitation. This tailored approach is important, as research has shown that while adequate volume resuscitation is imperative in the early care of patients with shock, once the shock is resolved, patient outcomes may improve with restricted volume resuscitation. These findings indicate that we should only give fluids to those patients who will respond to them with improved stroke volume; thus, we must be able to consistently predict which patients will or will not respond to a fluid bolus. Once a patient’s fluid status is optimized and if they are still hypoperfused, consideration should be given to further evaluate and support their cardiac function (inotropes or vasoactive medications).

“Research has shown that while adequate volume resuscitation is imperative in the early care of patients with shock, once the shock is resolved, patient outcomes may improve with restricted volume resuscitation.”

In the past ten years there has been a shift away from trying to achieve normal or supranormal levels for cardiac output and oxygen delivery. First, as we evaluate cardiac output, we need to shift away from the idea that there is a normal cardiac output; rather the cardiac output is either adequate or inadequate as indicated by the patient’s utilization of oxygen. We currently have two measurements that allow for continuous monitoring of oxygen balance (SvO₂ and ScvO₂). While research indicates that the two values are not interchangeable, the ScvO₂ does trend changes in SvO₂, and can be used as an indirect indicator of the adequacy of tissue oxygenation. Several goal-directed therapy studies have demonstrated the potential benefit of using these oxygenation indicators to evaluate the effectiveness of therapy. What remains unknown is whether these indicators need to be monitored continuously or whether intermittent monitoring will be adequate.

Another area of research is the development of technologies that allow us to look directly at a patient’s microcirculation and to measure oxygenation and perfusion indicators at the level of the tissue and even down to the level of the mitochondria. These areas of research are still developmental, but they are important because, despite normalization of blood pressure and heart rate and even SvO₂ or ScvO₂, the patient may still have impaired microcirculatory blood flow and occult hypoperfusion; and we know that these patients have worse outcomes than those patients who are adequately resuscitated as indicated by resolution of these problems. The challenge again will be to demonstrate that the integration of these markers into care improves patient outcomes.

**Trends in Education**

Many of the recent major advances in improving outcomes for critically ill patients focus on optimizing the patient’s cardiopulmonary status. The best example is the implementation of goal-directed therapy, which has been shown to improve outcomes for patients with sepsis and septic shock and for high-risk surgery patients.

In addition to the technical aspects of monitoring, education should guide newer providers through cases that demonstrate how to integrate hemodynamic data into the care of these complex patients and how to use hemodynamic data (both measures of cardiac function and the adequacy of oxygenation) to determine if the care provided is making a difference for the patient. Newer students also need to begin to develop their abilities to be smart consumers of the literature related to hemodynamic monitoring so they can understand the research designed to determine if (1) new technologies are accurate and reliable and will work in their patient population and (2) if care protocols that use these data to guide therapy actually improves patient outcomes.

Despite decreased use, invasive cardiac monitoring is not going away. There are patients who may benefit from PA pressure monitoring. The challenge will be to maintain our expertise in performing PA pressure monitoring, to include the technical aspects of care and the ability to interpret and use these data. The good news is that information is available on an educational website (PACEP.org) that was developed by major professional groups. We may need to think about creating teams of nurses who provide care for these patients, much as we have teams of nurses who care for patients requiring dialysis or support with a balloon pump.

While much of our education has emphasized PA pressure monitoring, we also have a very important need to maintain our ability to measure and interpret CVP readings as we transition toward increased use of this indicator.
Continuous ScvO₂ Monitoring Provides Early Warning of Cardiac Tamponade

This case report describes a 3-month-old infant with congenital cardiac disease who underwent successful defect repair at British Columbia Children’s Hospital. Prior to the surgical procedure, a 4.5 French dual-lumen PediaSat oximetry catheter (Edwards Lifesciences) was placed in the right internal jugular vein. Two days post-surgery, the patient’s ScvO₂ decreased from the mid 70s to the high 40s over a 3-hour period. There were no changes in heart rate, blood pressure, blood lactate levels, central venous pressures, or arterial blood gases. The ScvO₂ decrease was confirmed by co-oximetry and an echocardiogram revealed an inferior cardiac tamponade. Following surgical evacuation, the patient’s ScvO₂ increased to the upper 60–low 70 range. The patient recovered and was released from the hospital on day 11.

This case illustrates that traditional methods of assessment may be unreliable or respond slowly to changes in oxygen balance. The authors said, “Continuous monitoring of the ScvO₂ using the Edwards PediaSat oximetry catheter can provide an early indicator of changes in clinical condition in the critically ill pediatric patient population.”

Accuracy of PediaSat Oximetry Catheter Confirmed in Pediatric Cardiac Surgery Patients

A new central venous catheter designed for pediatric use (PediaSat oximetry catheter, Edwards Lifesciences) was evaluated at British Columbia Children’s Hospital and compared to lab-measured oxygen saturation. The PediaSat oximetry catheter ScvO₂ readings were compared to values from conventional co-oximetry monitoring in 8 subjects (age range 1 day to 11 years) who underwent cardiopulmonary bypass surgery. The researchers reported that ease of use, ability to deliver fluids and drugs, pressure monitoring, and blood sampling compared favorably to a conventional dual lumen catheter. Their data comparison yielded a mean percentage difference of 0.14% and precision of 5.4% between the two methods, leading to the conclusion that the PediaSat oximetry catheter provides accurate trending of ScvO₂ and functions well as a conventional catheter. The authors also said that the ScvO₂ continuous trend may serve as an early alert to changes in these patients’ clinical condition.


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Future Applications

To date most of the research involving these new technologies focuses on whether they are accurate and reliable indicators of whatever parameter they are measuring, for example stroke volume, pulse pressure variation or central venous oxygenation. This research is important to ensure that the technology we use is providing us with accurate and reliable information. As smart consumers of literature and patient advocates, we must ask the next question: Does integration of this information into the plan of care improve patient outcomes?

“Does integration of this information into the plan of care improve patient outcomes?”

As we gain a better understanding of the pathophysiology of syndromes such as sepsis and heart failure, there is increased appreciation of the need to monitor oxygenation not only at a macro level (e.g., SvO₂, ScvO₂ or lactate), but also at the tissue level, and to use these data to evaluate the effectiveness of our treatments. This area is intriguing, as new research is demonstrating that, in sepsis, it is the tissue hypoxia that is the trigger for worsening inflammatory response, so our ability to look directly to the cellular level to ensure adequate oxygenation will be important in evaluating the effectiveness of therapy.

As we move away from PA pressure monitoring, we have lost our ability to indirectly measure a patient’s risk for pulmonary edema. Newer methods are being developed to indirectly estimate lung water through bioimpedance or a series of calculations based on arterial pressure waveforms. The accuracy and utility of these new indices remain to be demonstrated, but these indicators may be particularly useful in patients with heart failure, ARDS, blast lung injuries or for optimizing the physiological status of an organ donor.

Evidence-based practice is about integrating evidence with clinical expertise. We need to continue to educate nurses not only about the protocols, but also the evidence behind the protocols and how to critically evaluate each patient to ensure the appropriate application of the evidence into their care.

"Does integration of this information into the plan of care improve patient outcomes?"
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What do you do with hemodynamic data?
See an expert’s suggestions, pages 1 & 6.

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