Critical Connections

The Complete News Source for Critical Care Professionals

Society of Critical Care Medicine

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Worldwide.

In This Issue February 2004

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Bioterrorism and Critical Care Medicine: Are We Prepared?

Since 2001, the U.S. medical community has taken renewed interest in bioterrorism. The potential for a frightening variety of unfamiliar biologic and chemical weapons to be used within the United States is clear. Preparing for bioterrorism requires a carefully planned approach across the healthcare industry, involving initiatives from the federal government, state and local health authorities, and individual hospitals and healthcare practitioners. The Society of Critical Care Medicine (SCCM) and ICU directors continue to be active leaders in addressing the bioterrorist threat.

Continuing medical education courses and medical literature describe scenarios with which critical care specialists can become familiar, the precautions that must be taken to contain these biohazards, the responsibilities practitioners have to their communities, and the obligation to alert law enforcement agencies when a bioterrorist threat is first suspected. The Society has responded organizationally through its new publication,

(see Bioterrorism and Critical Care Medicine: Are We Prepared?, page 7)

Two Hospitals Prove Disaster Preparedness



Although hospitals drill and plan for disaster response, nothing but a true disaster can test systems and help fine tune preparedness plans.

Washington Hospital Center (WHC), in Washington, D.C., was challenged by the events surrounding the September 11, 2001, terrorist attack on the Pentagon, while Massachusetts General Hospital (MGH) tested its disaster plan in the aftermath of The Station nightclub fire on February 20, 2003. Both institutions report their drills and planning served as excellent preparation, but some minor adjustments have been made in retrospect.

Washington Hospital Center received the major burn victims from the Sept. 11 terrorism-related plane crash into the Pentagon. Fortunately, WHC staff had been immensely proactive in disaster planning – especially for mass disaster or bioterrorism – before the events of Sept. 11. The Pentagon experience along with the organization's comprehensive disaster plan helped advance disaster preparedness efforts.

Washington Hospital Center admitted the Pentagon's nine burn patients. Society of Critical Care Medicine (SCCM) Member Arthur St. Andre, MD, FCCM, who is responsible for five surgical intensive care units with a total of 50 surgical ICU beds and nine intermediate care beds, was triage officer that day. He recounts WHC's preparation and response efforts.

(see Two Hospitals Prove Disaster Preparedness, page 9)

Drug Shortages in Critical Care

In the past five to 10 years, drug shortages have become increasingly prevalent and are now commonplace in the healthcare arena. The impact is vast and extends far beyond lack of a given drug for a given patient. It is important to identify the origin of drug shortages and the overall impact on both the patient and the healthcare organization, in particular, the academic medical center. In addition, staying abreast of current drug shortage information and potential therapeutic alternatives is paramount for critical care practitioners.

In November 1997, the United States experienced the start of an ongoing shortage of intravenous immune globulin (IVIG). From that time period to present, shortages of medications, particularly those that impact critical care settings (e.g., IV antibiotics, IV corticosteroids, neuromuscular blockers) have persisted. Several reasons have been attributed to these drug shortages, including manufacturing, discontinuation of products for economic reasons, supply/demand imbalance, raw material shortage, and regulatory issues. Of particular frustration is the discontinuation of products purely based on economics (i.e., low-cost generic products). The Food and Drug Administration (FDA) has no authority to force manufacturers to continue to produce a product even in the best interests of the public. However, it has been strongly advocated to the FDA to provide incentives to companies to continue the production of less profitable, routinely used medications.1

The impact of a drug shortage is extraordinary and often involves compromised patient care and clinical outcomes, as well as an increased risk for medication errors. Most often, therapeutic alternatives are identified in times of a drug shortage, which creates a scenario where medications utilized are less familiar, may be inappropriately dosed and monitored, and/or delays in treatment occur usually due to communication inefficiencies to healthcare providers.



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Critical Connections' mission is to provide members of the Society of Critical Care Medicine and critical care professionals with timely information regarding the practice of critical care and the Society's activities.

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Society of Critical Care Medicine

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Message from the editor



Emerging Issues in the ICU: Pathogens and Bioterrorism

Frederick P. Ognibene, MD, FCCM Clinical Center, National Institutes of Health Bethesda, Maryland, USA

The intensive care unit (ICU) has always been considered a dynamic clinical environment. Patients frequently enter the ICU with complex illnesses and a wide range of pathophysiological variables, many of which are not necessarily predictable, and which complicate and impact management and care. In addition to this realm of physiologic unpredictability, we have recently been thrown into the realm of the "unknown" in our ICUs because of the emergence of new diseases, due to both infectious and non-infectious agents. In addition, some recent instances of large-scale disasters caused by humans do not necessarily reflect the emergence of new diseases, but by the nature of their etiology and magnitude have to be handled on an emergent basis in the ICU.

In this issue of *Critical Connections*, several articles provide excellent examples of these emerging problems. For example, SARS is presented in one article as a paradigm of emerging infections. Resistant bacterial pathogens and West Nile virus are two more examples of contemporary infectious diseases that are affecting patients in ICUs and are also taxing hospital resources. At the other end of the "emerging" spectrum, we appreciate the impact of two man-made problems, the terrorist acts of September 11, 2001 and the conflagration at The Station nightclub in Warwick, Rhode Island. Both events led to a rapid influx of critically ill patients into surgical intensive care units, while also testing the disaster preparedness systems of large urban medical centers. In addition, the cover article discusses infectious as well as non-infectious causes of bioterrorism and the responsibilities of the critical care community. Prior to the events of September 11, 2001 the impact of terrorism on ICUs was speculative; today it is a reality.

Clearly, as healthcare professionals working in intensive care units, we have to be ready for both natural and man-made situations. A better understanding of and an organized approach to these infectious and non-infectious issues will allow us to better care for our patients and to manage extremely limited resources, human and otherwise. This issue of *Critical Connections* addresses the impact of emerging pathogens and bioterrorism and encourages all healthcare practitioners to learn more about these issues so that they can improve patient care, better manage resources and improve disaster preparedness. \triangle

Message from the president



Timothy G. Buchman, MD, PhD, FCCM President Society of Critical Care Medicine

Dear Friends,

This is my last *Critical Connections* column as president of the Society of Critical Care Medicine (SCCM). I write to share some closing thoughts about our profession, our society and our future.

Our Colleagues

Three weeks ago, I was visiting a colleague's ICU. A young surgeon with an interest in emergency medicine and critical care presented the case of a motorcycle crash patient battling multiple organ dysfunction syndrome. Six weeks into the clinical course, the patient had developed hypotension that was refractory to fluid administration, deep jaundice, an enervated immune system, and the catabolic weakness of chronic critical illness. Electronic data systems at the bedside made it easy to check physiologic and laboratory data. Highquality images were immediately available for review. We and others on the ICU team discussed the growing recognition of corticosteroid insufficiency in critical illness, outlined strategies for interrogating the hypothalamic-pituitaryadrenal axis, and suggested possible treatment regimens. My colleague sent me a note yesterday explaining that the patient seemed to respond nicely to the corticosteroid trial, is in good spirits and seems to be on the mend.

I mention this vignette because my colleague, his ICU and the patient all happen to be about 8000 miles away - in Japan. During my year representing SCCM, I have visited dozens of colleagues and their ICUs around the world. There have been two constants among these visits. First, outstanding critical care exists worldwide. I have been welcomed by each organization and have found teams of professionals that base their decisions on solid clinical science and deliver their bedside care with great compassion. Second, around the world we share the same challenges (such as caring for aging populations and balancing the ICU budgets) and treat the same diseases.

Tomorrow is Yesterday

My point? The next time you attend an international meeting - such as the Society's Annual Congress - and you encounter a delegate from another country, take the initiative and introduce yourself. Both of you are attending the meeting as critical care professionals. Tell your international colleague a little about the ICU where you work, the types of patients you manage and the challenges you face. Ask about their homeland and professional lives. Offer a business card. Many of my enduring professional friendships originated from such chance encounters. I'm confident you'll make new friends as well.

Our Public

About halfway through the flight to Japan — somewhere over the Bering Sea — the public address system aboard the 747 came to life with, "If there is a licensed physician aboard the plane, would you kindly ring your call button ... " I did, and I was asked to see a young attorney who was having an acute allergic reaction. She was developing a rash, her face was a little swollen, but she had a good airway and had no trouble breathing. Fortunately, the medical kit on board the aircraft contained both diphenhydramine and epinephrine. Even more fortunately, a little of the former was sufficient to resolve the problem and keep the plane on course to Osaka. But for the half-hour or so that I kept an eye on her symptoms to ensure they were resolving, I bent her ear — and the ears of some of the cabin crew — about what I do as an intensive care professional.

Each of them knew about cardiologists. All of them watch "ER." I told them that one of the other "hats" that I wear was that of trauma surgeon — they knew what that was, too. But not one of them knew about the discipline of intensive care medicine and its practitioners, leading me to conclude that the public's lack of knowledge about critical care medicine is pretty widespread.

My point? All of us have interesting and exciting careers. All of us educate during professional encounters — we spend a lot of our time teaching patients and families about aspects of critical care medicine. But how often do we take the opportunity to tell the general public who we are, what we do and why we are important to them and to their loved ones? If you have a chance, talk to your community group. Speak at your child's school. Write an opinion piece for your local newspaper. Tell them what a critical care professional is, and why your contributions are meaningful to you, to them and to your community. And if you have the chance to meet face-to-face with legislators, policymakers and other opinion leaders, let them know too.

Our Future

I recently received the following note: Dear Dr. Buchman,

I am sure you won't remember me, but I am Mrs. D. G....'s son. You took care of her in the ICU at Barnes Hospital six years ago. She had a severe infection and shock after an emergency operation on her colon. (I was the son who was called back to St. Louis from boarding school. My brother is the one who is an architect.) Mom is fine, and we all remain so grateful for your care, but that's not why I am writing.

I had always thought about becoming a doctor, but Mom's experience cinched my decision. I just got accepted to medical school. (It's my first acceptance, and I have several more applications out there.) I don't know what kind of doctor I want to be just yet, but I am thinking about becoming an ICU doctor like you.

Now here's why I am writing. I don't really understand the ICU training process. None of the medical school Web sites talk about residency training in ICU medicine. What am I missing? Respectfully, B.G.

"If you have a chance, talk to your community group. Speak at your child's school. Write an opinion piece for your local newspaper. Tell them what a critical care professional is, and why your contributions are meaningful to you, to them and to your community." The truth is, I didn't remember him until he mentioned the particular boarding school he attended. (He often wore that school's sweatshirt in the waiting room.) I barely remember his mom — it was "thousands of patients ago," and someone else was the operating surgeon. That didn't diminish my pleasure in receiving the note, though!

What I found distressing was what I had to write this young man in reply, namely that there is no primary residency training in critical care medicine in the United States. If he wants to become an ICU doctor, he will have to choose something else first — internal medicine, anesthesiology, surgery, or pediatrics. After he finishes training in one of these disciplines, then and only then can he go on and train to become an intensivist.

Will his interest in critical care medicine survive medical school and initial training in another discipline? I don't know. But I wonder how many other young people similarly excited about careers in critical care medicine are ultimately dissuaded from that goal because there is no direct training path. Medical school is not cheap — debt accumulates through residency training, and the long two-stage (residency plus fellowship) training approach is not particularly attractive.

My point? If a candidate wants to initially train in another discipline, that's great and we have well-established pathways and programs. But for the medical student who is sure that s/he wants to become an intensivist, there ought to be a direct and efficient route. We can ill afford to discourage potential future intensivists with prolonged and circuitous training schemes.

In closing, I send my special thanks to the editorial and production staff at *Critical Connections* for their skills in helping produce this column. They have kept me on schedule issue after issue and have helped me preserve the flying moments of practicing critical care.

Tomorrow has become yesterday. It is with greatest pleasure that I turn over the stewardship of this column — and of the Society — to Margaret Parker, MD, FCCM, the Society of Critical Care Medicine's next president. △

How Can We Learn from Incidents?



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Patient safety and quality care have become important issues in healthcare, particularly critical care. The Society of Critical Care Medicine (SCCM) is committed to advancing this healthcare initiative and, as a result, created an Advisory Review Panel on Patient Safety. This Panel is made up of ICU physicians, nurses, respiratory therapists, pharmacists, and other safety researchers. The charge of this Panel is to:

- Review cases from the Intensive Care Unit Safety Reporting System (ICUSRS) project (an anonymous Web-based incident reporting system)
- Discuss ways to improve safety using panel member expertise and evidence-based medicine
- Broadly disseminate their findings to the critical care community

The ICUSRS project is an incident reporting system that currently collects data on adverse events and near misses in 23 intensive care units in the United States. The reporting process is voluntary, anonymous to reporter and patient, and the data collected is kept confidential. This project is directed by Peter Pronovost, MD, PhD, who is also the chair of SCCM's Advisory Review Panel on Patient Safety.

The Panel's format for disseminating information is to select a case illustrative of a safety issue, provide a case overview, dissect and pull out the multiple system failures that contributed to the incident, and provide safety recommendations designed to decrease the likelihood of recurrence. Using this format, the following is an example of an adverse event analyzed by the committee.

Adverse Event: Inappropriate Ventilation Support

Case Overview

Critical Connections

A 63-year-old trauma patient arrived from the emergency department with abdominal distension and deteriorating respiratory status. On initial evaluation, it was found that the patient suffered from duodenal trauma and perforation. The patient's respiratory status progressively declined, prompting the clinical staff to manually ventilate the patient using a bag valve mask. Failure to improve the patient's respiratory status, which was a direct result of his/her abdominal distension, was met with more aggressive manual ventilation. The intensivist arrived, noted the aggressive ventilatory management and worsening abdominal distension and immediately altered the ventilation process. Prior to intubation, the patient aspirated gastric contents into the right lung and subsequently developed ARDS.

In evaluating this incident, five system failures contributed to patient injury. Furthermore, each system failure had an impact on the next, like a domino effect, resulting in the patient developing ARDS. First, let's dissect this case and then use James Reason's 'Swiss cheese model' to capture a visual of this adverse event.¹ In this model, the holes represent latent organizational vulnerabilities; when these vulnerabilities align and defenses break down, harm can occur.

System Analysis

System Failure 1: *Poor Communication.* Although it is not clear from the report what transpired at the time of transfer, staff should have communicated with senior staff to assess the patient's airway status before transfer. And, airway should have been secured using an endotracheal tube prior to transfer from emergency department to ICU (**System Failure 2:** *Transfer guidelines*).

System Failure 3: Lack of supervision during transfer and inadequate training and mix of staffing skills (**System Failure 4**) led to poor decision making and clinical management. The patient's airway should have been ventilated by face mask until saturations were adequate and then intubated if needed. The patient's deteriorating condition should have been monitored more closely. In the absence of staff trained in intubation, other options should have been available (e.g., laryngeal airways) and manual ventilation altered to limit gastric insufflation.

System Failure 5: *Poor ventilation technique.* Previous evidence has shown that manual ventilation with a self-inflating bag and face mask was a poor choice because this method can result in gastric distension (an initial diagnosis for this patient), reduced chest wall compliance, alveolar hypoventilation, and an increased risk of aspirating gastric contents (the harm this patient experienced).^{2,4}

System Failure 6: *Inadequate patient monitoring* made it difficult for the staff to notice the worsening of this patient's abdominal distension, which caused aspiration and subsequent ARDS.⁵

Reason's Swiss cheese model⁶ is based on the premise that incidents in healthcare are complex, and rarely involve one action or system failure. Each slice of cheese in this model represents a specific element in the delivery of care (e.g., ventilating a patient). The slices are riddled with imperfections or breakdowns in each element of the system (e.g., proper staff training to perform a ventilatory procedure). These breakdowns are represented by the holes in the cheese slices. When the holes line up, an adverse event occurs.



Safety Recommendations Staff Training and Education:

- All clinical staff should be trained in basic life support using ECC/AHA guidelines.⁷ Trained staff should also be inserviced annually and/or when standards of care change. In the case of ventilation, training should emphasize proper methods for manual ventilation (e.g., smaller tidal volumes, low flows or squeezing bag slowly, low airway pressures and use of cricoid pressure for prevention of abdominal distension).^{8,10}
- All clinical staff with patient interaction should know all of the options available for airway management (e.g., laryngeal mask airway, cuffed oropharyngeal airway (COPA) and Combitube)¹¹ and consider simulation training to gain experience in the use of the equipment.

Policies and Procedures:

- Change hospital policy to allow allied health professionals to intubate patients in an emergency situation when a physician is not available. In many hospitals, respiratory therapistscan perform endotracheal intubation.
- Change policy to require patient monitoring of airway pressure during manual ventilation. To avoid gastric distension, note that airway pressure should be less than 20 cm H2O, given you can maintain adequate oxygenation.¹²

To improve patient safety, we must learn what is broken, through incident reporting, and use that information to change our systems. In an effort to present the lessons learned from a case, the Advisory Review Panel has adapted this case to a one-page summary sheet (Figure 2) that can be posted on a bulletin board or used in presentations. The Society would like to know which methods of summarizing incidents are most useful to you and would appreciate your feedback on the methods that best facilitate improvements in safety (email nstonis@sccm.org with your feedback).

The Society will continue to dedicate an article in *Critical Connections* for disseminating safety suggestions made by the Advisory Review Panel on Patient Safety. Future articles will address both adverse events and near misses and will include case presentations. Our goal is to help you improve patient safety in your ICU.

Acknowledgements

We would like to acknowledge all the other members of the Advisory Review Panel on Patient Safety for their contributions; including, Paul Barach, MD; David Kaufman, MD, FCCM; Lynn Kelso, MSN, APRN, BC; Ruth Klienpell, PhD, RN-CS; Lisa Lubomski, PhD; Diane Lyle, BS, PharmD; Steve Martin, PharmD, FCCM; Patricia McGaffigan, RN, MSN; Nancy Stonis, RN, BSN, MJ; Ann Thompson, MD, FCCM; and David Thompson, DNSc, MS, RN.

References are available at SCCM's Web site, www.sccm.org/publications.

Drug Shortages in Critical Care

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For example, the ongoing shortage of methylprednisolone has necessitated the use of other parenteral steroids (also sporadically unavailable due to the increased demand). While therapeutically equivalent for the majority of indications, these drugs are dosed differently, have varying stabilities and IV push rates of administration. Unfortunately, this variability creates an environment for error. For example, the unavailability of parenteral prochlorperazine has led to an increased use of parenteral trimethobenzamide. Although prochlorperazine may be administered IV push, trimethobenzamide can only be given intramuscularly. It can be anticipated that a clinician might inadvertently administer trimethobenzamide intravenously when he/ she considers it the alternative to prochlorperazine.

In addition to patient outcome, healthcare professionals continue to be concerned about the tremendous resources needed to address each and every shortage. These concerns may be magnified in large, academic medical centers due to the sheer numbers of professionals to inform, as well as those needed to develop a rapid consensus regarding alternatives. Typically, a shortage is either identified by a pharmacy purchaser or via communication in professional societies. From this point forward, it is necessary to carefully investigate the validity of the information, the potential impact on patients in specific medical centers based on current use, supplies available, and anticipated shortage duration.

Once this information is evaluated, the problem-solving exercise becomes more clinically oriented and less focused on drug procurement. Although not a function exclusive to the Pharmacy and Therapeutics (P&T) Committee, such a group is a logical choice for coordinating development of therapeutic alternatives and methods for communication to the healthcare staff. Addressing the shortage and appropriate alternatives must occur quickly and, if limited supplies are available, a plan to restrict use or pool supplies is often immediately required. Medical centers must proactively identify designated personnel (e.g., P&T chairperson, pharmacy director, pharmacy purchaser, etc.) to coordinate this process. A proactive approach and streamlined process is especially needed to facilitate resolution of drug shortage issues involving critical care medications.



Although the academic medical center may have specific challenges due to the larger numbers of medical personnel, centers with multiple sites, specialties and services also have some advantages. When drugs are subject to limited distribution, all sites/services can purchase a given allotment, yet pool supplies for the most critical needs. For example, methylprednisolone may be acquired by an obstetrics hospital, but reserved for spinal cord injury for its "sister" trauma hospital. Penicillin might be purchased by all adult sites, but reserved for neonates at a sister site. In addition, professionals at academic centers are likely networked with colleagues around the country and can seek assistance regarding alternatives that can eliminate unnecessary duplicative work.

Fortunately, a number of online resources can assist in providing current information regarding shortages and recommended therapeutic alternatives. These include the FDA, www.fda.gov, the Centers for Disease Control and Prevention (CDC), www.cdc.gov, and the American Society of Health System Pharmacists (ASHP), www.ashp.org. Despite these advances, drug shortages continue to plague an already overstressed inpatient healthcare environment. They exhaust precious healthcare personnel resources, are costly and most importantly, can be detrimental to patient care. Δ

References are available at SCCM's Web site, www.sccm.org/publications.

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Bioterrorism and Critical Care Medicine: Are We Prepared?



Henry Masur, MD, FCCM National Institutes of Health Bethesda, Maryland, USA

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Fundamentals of Disaster Management, along with its Web site that provides important, readily accessible information with links to useful sites such as the Centers for Disease Control and Prevention (CDC). All practitioners should be familiar with SCCM's Web site, www.sccm.org, so they can refer to it when suspicious or alarming clinical events first occur.

During the winter season, clinicians are faced with a particular challenge. The major bioterror concerns involve agents categorized by the CDC as "Category A," i.e., agents that can be easily disseminated or that can be readily spread from person-to-person. Infection from these agents often results in high mortality, thus having great potential to cause not only illness, but also public panic and social disruption. Among the seven major types of agents included in Category A, anthrax, plague, tularemia, variola and even certain viral hemorrhagic fevers could be confused with influenza, or some other relatively trivial respiratory illness, early in their course.

For most respiratory illnesses, especially those that are not severe and that occur in otherwise healthy individuals, common and reasonable medical practice is to make an empiric diagnosis and initiate empiric therapy. This strategy is appropriate in many situations, yet empiric diagnoses do not permit unusual diseases or new epidemics to be recognized. Specific diagnoses can be beneficial for such diseases as influenza. When the first cases of influenza appeared relatively early in the fall of 2003, clinicians who made specific diagnoses were able to initiate an appropriate anti-influenza drug for these early patients, and to contribute important information to health authorities.

This early detection allowed healthcare authorities to alert the public to get vaccinated, and to alert governmental agencies of the need to produce or acquire supplemental supplies of vaccine. This early detection of influenza also reinforced the need for healthcare practitioners to consider the diagnosis of influenza in subsequent patients: the efficacy of oseltamivir or rimantidine diminishes rapidly the longer the patient has been symptomatic prior to therapy. Through efficient communication, practitioners were able protect themselves and their staffs by initiating appropriate isolation precautions and encouraging staff to become immunized or to take chemoprophylaxis.

While the federal government has a surveillance system for detecting influenza, and while healthcare practitioners have been trained to think of influenza as a treatable cause of respiratory illnesses in the late fall and winter, the experience with anthrax in 2001 suggests that the first victims of a bioterrorist attack often fare poorly because there is no surveillance system, and clinicians do not consider the diagnosis until the initial victims have life-threatening disease, or have died. Even if agents of bioterrorism are considered, tests for such agents are not readily available, and there is considerable economic and administrative pressure *not* to perform such expensive tests unless they can be readily justified. When the first cases of inhalational anthrax were seen in 2001, there was no epidemiological reason to suspect anthrax, nor were rapid diagnostic tests readily available. In most circumstances the patients would, in their early phases, be considered to have a viral respiratory infection, and dismissed without therapy or with a broad spectrum antibacterial agent, especially in the early fall before the start of the influenza season. When clinicians in Florida recognized Gram-positive bacilli in blood and cerebrospinal fluid, they astutely considered anthrax, and alerted law enforcement officials and public health authorities to a new pathogen in their community. That recognition allowed other clinicians to watch for potential victims and to initiate treatment promptly.

"Preparing for bioterrorism requires a carefully planned approach across the healthcare industry..."

However, the subsequent experience with anthrax attacks in the Washington, D.C. area taught some valuable lessons. Initial cases were not recognized promptly. Public health authorities tried in good faith to accommodate public anxieties, but in some cases they made statements based more on hope than data that turned out to be wrong. The lessons learned were first, the state of knowledge about biologic and chemical agents delivered by novel technologies and routes needs to be expanded. We need to fund and publish information, for example, on the pathogenesis of aerosolized anthrax and the mechanisms of action of anthrax toxins. In 2004 we have very few national facilities that can perform spore challenges of animals even if funds to conduct appropriate experiments were available.

Secondly, knowledge of what is known must be available and accessible. Federal officials who managed the Capitol Hill attack deserve enormous credit for initiating an effective program of chemoprophylaxis and education even though their initiatives were based on logic rather than data. Mobilizing the resources to determine what should be done, to perform the necessary cultures for a huge number of potentially exposed employees, and to safely administer chemoprophylaxis was an undertaking that many public health authorities are still ill equipped to lead. Third, news about the presence of an attack must be widely disseminated immediately. Clinicians, including intensivists, must be told that a new pathogen or chemical agent could be in their geographic area so that they can look for new target populations and new presentations, and so that appropriate therapy and isolation precautions can be initiated promptly. Fourth, tests for such agents must be readily accessible and have a rapid turnaround.

In the Washington, D.C. area in 2001, there was no organized method for notifying emergency rooms, practitioners and ICUs that a postal worker appeared to have anthrax in Virginia, making it difficult for health practitioners to recognize early manifestations of anthrax in other parts of the region and potentially compromising patient outcome. Failure to recognize cases early had dire consequences for patients. For staff, anthrax is not transmissible person-to-person. Had the attack been with aerosolized plague, or variola, however, nosocomial outbreaks could have devastated healthcare facilities, much like SARS did in Asia and Toronto.

The United States, as a global leader in biomedical research and as a prominent potential target of bioterrorism must fund research to answer pivotal questions about transmission, pathogenesis, diagnosis, treatment, and prevention. Such research will require investment in facilities and personnel. With the vocal support of professional organizations such as SCCM, along with critical care leaders, findings can be promptly dispersed to the healthcare community. Much research appears to have been done worldwide by military organizations in the past, but these findings have not been made public, thus depriving civilian populations of the opportunities to take advantage of such work. The United States, as a likely target, must continue to fund and develop networks to communicate news of emerging pathogens, be they man-made or "naturally occurring," so that appropriate action can be taken.

As healthcare professionals, we must also be prepared to assume some personal risks in dealing with bioterrorist attacks. The response of SCCM in mobilizing resources for the September 11, 2001 attacks and the responsiveness of membership to providing care in an environment with unknown perils were impressive. The performance of ICU staffs in Toronto and in Asia during the SARS epidemic was also remarkable in terms of the willingness of staff to assume risk in order to perform their professional duties.

Critical care staff must have clearly thought through their professional responsibilities. By choosing healthcare as a profession, like policemen and firemen, individuals inherently accept a higher degree of risk to their safety. Because patients in the hospital pose some risk in terms of transmitting potentially lethal pathogens, critical care professionals cannot abandon their duties. To avoid staff disruption, however, ICU leadership must engage their staff in thoughtful discussions of this risk. Leadership must also provide the tools for staff to maximize their safety, i.e., have properly engineered facilities such as negative pressure rooms, and adequate equipment such as N-95 masks and gowns and gloves. They must have carefully thought through the complicated issues of pre-event immunization (e.g., for smallpox, anthrax or plague), and their approach to chemoprophylaxis, quarantine and isolation when events in fact occur.

In 2004, the critical care community is far better prepared to face the challenges of bioterrorism than it was in 2001. The absence of an attack since 2001 should not diminish our efforts to build better systems for recognizing and containing such events, and for alerting our colleagues about the risks that they and their patients may encounter. These systems are, in most respects, the very same systems that we need for dealing with infectious threats to our community that were not intentionally created, i.e., agents considered to be "emerging pathogens." The Society continues to provide strong leadership, and in our own ICUs, hospitals, and communities, we must continue to be part of the process that rapidly improves our ability to respond to emerging threats that will likely challenge us again.

Reduction of Antimicrobial Resistance in the ICU through Antimicrobial Stewardship





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"Part of the success in decreasing bacterial resistance at Methodist Hospital has been through the emphasis placed on appropriate antimicrobial selection." ntimicrobial resistance is a burgeoning problem in the ICU. Resistance may be carried from extended care facilities and long-term acute care hospitals, and even from the community, as excessive antimicrobial use alters bacterial susceptibility. Automatic isolation of patients from high-risk facilities until resistance is ruled out may be a necessary measure to minimize spread of such pathogens.

Additional measures are needed to minimize the risk for nosocomial resistance. Antimicrobial stewardship involves the appropriate but judicious use of antimicrobials along with sensible selection of agents to maximize bacterial killing while minimizing the selective pressure that leads to resistance. A systems approach to prevent and control the emergence and spread of antimicrobial-resistant microrganisms in hospitals was outlined in 1996, but like many guidelines, full adherence to the recommendations has lagged.¹ The proposed strategies include developing a system to track and report trends in antimicrobial resistance; developing a system for rapid detection of resistant microorganisms in individual patients; increasing adherence to policies and procedures such as hand hygiene, barrier precautions and environmental control measures; prioritizing control of bacterial resistance within the organization's strategic plan, and developing a plan to properly identify patients who are colonized with resistant pathogens (Table 1).

Methodist Hospital, a Clarian Health Partner in Indianapolis, Indiana, recognized increasing Enterobacter, Enterococcus and Pseudomonas resistance in 1995. This private teaching facility has over 100 adult ICU beds, a 24-hour intensivist-directed critical care service and four critical care pharmacists. To address increasing resistance, a collaborative approach involving infectious disease (ID) physicians, an ID pharmacist, and the Microbiology Department was initiated in 1995. The goals of the antibiotic utilization program are to improve patient outcomes, reduce antimicrobial resistance and decrease antimicrobial expenditures. These goals can be accomplished by drawing on the expertise of the core committee with the assistance of other clinical pharmacists and staff physicians.

The microbiologist has knowledge of the appropriate testing of specimens, the appropriate techniques to determine bacterial susceptibility, and the current ecology of the hospital. Resistance patterns are trended over time with annual antibiogram reports, and more frequent evaluations of unusual pathogens. The ID pharmacist employs his or her knowledge of antimicrobial pharmacokinetics and pharmacodynamics. The ID physician also provides expertise in the evaluation of these data and applies it to patient care.

Part of the success in decreasing bacterial resistance at Methodist Hospital has been through the emphasis placed on appropriate antimicrobial selection. This goal is achieved in multiple ways, none of which include antibiotic restriction. The antimicrobial formulary at Methodist Hospital includes agents from each antimicrobial class with varying spectrums of activity, although duplication of similar agents from the same class is minimized. The Antibiotic Subcommittee and the Pharmacy and Therapeutics Committee add new agents to the formulary only after interdisciplinary review. Agents are assessed based on pharmacokinetic and pharmacodynamic properties, likelihood of inducing resistance or adverse events based on structure activity relationships and the potential impact on cost. However, in some cases, using an agent with a more costly acquisition price may be more costeffective in the long run, if resistance is minimized and antibacterial efficiency is greater. The committees update antimicrobial usage guidelines regularly.

Once the plan for antimicrobial use was developed, and with each revision, educational sessions are held with the medical staff to encourage appropriate antimicrobial selection that will maximize patient outcomes and prevent resistance. Critical care pharmacists, with the support of the ID pharmacist, evaluate antimicrobial prescribing, examine culture results and discuss how to optimize the regimen with physicians. This antimicrobial stewardship has discouraged the use of agents that promote resistance, in particular fluoroquinolones and third-generation cephalosporins, and has endorsed the use of extended spectrum penicillin/ beta-lactamase inhibitors and aminoglycosides. A pharmacy-based aminoglycoside dosing program coupled with individualized, extended-interval dosing maximizes the efficiency of bacterial killing with minimal adverse effects. Close monitoring and dose adjustment with changing clinical status avoids pre-dose concentrations above 0.5 mg/L and routinely achieves concentrations of 10 times the MIC. This approach was described originally at Hartford Hospital and improvements in safety and efficacy have been demonstrated.²

One example of the impact on resistance patterns was illustrated with pathogens in the Enterobacter group. Prior to 1995, third-generation cephalosporins were routinely used for empiric and therapeutic indications. Enterobacter resistance had increased (Figure 1), leading to increased use of fluoroquinolones, primarily ciprofloxacin. While the efficacy of fluoroquinolones against Enterobacter was impressive, a trend toward increased Pseudomonas resistance followed (Figure 2). The antimicrobial plan was then revised to also avoid empiric fluoroquinolone use and instead use macrolides for atypical pneumonia coverage, along with extended-spectrum penicillins and individualized dosing of extendedinterval aminoglycosides. This effort has gradually reduced Pseudomonas resistance (Figure 2).

Infection control programs that include alcohol-based hand disinfectants have been utilized since 1997 as an adjunct to handwashing. Extensive education to minimize ventilatorassociated pneumonia (VAP) has produced a dramatic reduction in VAP rates. Oral hygiene, head-of-bed elevation, and correct ventilator tubing positioning are components of that initiative. Nursing and respiratory care involvement and support of these initiatives is essential.

While the benefits of minimized resistance are apparent to critical care practitioners, the impact on costs cannot be ignored. Through these ongoing efforts, the cost of antimicrobials within the institution has not increased since these programs were established, despite the increase of more expensive agents (Figure 3). However, continued vigilance for the presence of emerging pathogens, such as Acinetobacter, or extendedspectrum beta-lactamase producing organisms is necessary. A coordinated response from the microbiologist, infectious disease physician and pharmacist, along with implementation of a therapeutic plan developed by the critical care team will be needed to maintain this success. Δ **References are available at SCCM's** Web site, www.sccm.org/publications.

Two Hospitals Prove Disaster Preparedness

(continued from page 1)

He recalls: "When we looked out the hospital window we could see the smoke from the Pentagon. The call came and our helicopter was the first medical service on the scene. We quickly flew two Pentagon burn victims to Washington Hospital Center. Unfortunately, we were not allowed to fly back because all nonmilitary air traffic was shut down. The additional seven patients were transported to us by ambulance." The discontinuation of medical helicopter service may have been the first unanticipated disasterrelated change in response.

Washington Hospital Center found that previous disaster preparations and drills were incredibly helpful. Automatically, patients scheduled for elective surgery were sent home and surgeries not fully started were cancelled to open the operating rooms for the Pentagon burn patients. Clinicians were immediately available in their assigned staging areas, and teams were dispatched to the disaster receiving area.

"We had a command center in our administrative office that set up a single source of communication to look for resources such as beds, supplies and personnel," says Dr. St. Andre, director of surgical critical care services at WHC. "We had done enough planning and drilling that all of the typical preparations went exceedingly well."

During the disaster, the authorities shut down the local telephone area codes. Dr. St. Andre said there presumably was a concern that a regional phone number might trigger a bomb. When the incoming calls were shut off, the internal phone system at the hospital closed down entirely. All phone communication was lost. "This was a situation we never considered during our planning," Dr. St. Andre comments.

Lessons learned from the Sept. 11 events helped Washington Hospital Center improve its disaster preparedness plan. For example, the loss of telephone communications within the hospital made triage and spreading other information much more difficult. At the time, the hospital was not set up on a walkie-talkie system, however, key WHC people in a disaster now carry walkie talkies.

"September 11 also helped us to better define our triage process during normal hospital operations," explains Dr. St. Andre. "Determining which bed a patient will be assigned to and when the patient can be moved into that bed is a complex process that combines a variety of people including the admitting office and nursing communication. After Washington Hospital Center lost all telephone service during the disaster, we had to find a way to streamline moving patients from the disaster resuscitation area to beds. One of the disaster leaders designed the new triage system on the fly."

Under the new process, when disaster resuscitation receives word that a patient has been assigned a bed, this communication signifies that the bed is now ready and the patient can be transported immediately. The new protocol streamlined the system and eliminated several unnecessary phone calls to the resuscitation area. A patient-labeling system was also developed that indicates whether or not the patient is ready for assignment. This system helps the resuscitation triage officer know when to call for a bed.

The hospital, with the financial support of the federal government, continues to study the impact of biological and chemical disasters and terrorism on healthcare organizations under its ER1 program. This effort includes facility design for disasters and the study of how to scale resources to meet both large and small disaster events.

Massachusetts General Hospital Successfully Responds Under Pressure

"Massachusetts General Hospital, a 900-bed facility, has an enormous depth and breadth of critical care resources that is probably unparalleled in most other tertiary care facilities," says Society of Critical Care Medicine Member Katie Brush, RN, MS, CCRN, FCCM. "Additionally, Massachusetts General Hospital is a Magnet Hospital that specially recruits, rewards and appreciates nurses. These two factors combine to provide strength and flexibility in all areas, but specifically in disaster response."

Indeed, MGH's disaster preparedness was put to the test earlier last year, when it responded to The Station nightclub fire in West Warwick, Rhode Island, that injured 200 people and killed another 100 people. MGH treated 14 critically ill burn patients and numerous outpatients.

"If you pare a hospital down to the bare bones, I do not know how it would be able to respond to a major disaster," continues Ms. Brush, a surgical critical care clinical nurse specialist on a 20-bed Surgical ICU at MGH. "The Station nightclub fire impacted the entire hospital, although only two units were caring for those patients."

Massachusetts General Hospital has a five-bed burn ICU, and six patients were directed to other units within the hospital. Five were sent to the surgical ICU – the burn unit backup – and one patient was treated at the medical ICU until the following day, when he was transferred to the surgical ICU. The hospital created burn patient cohorts to coordinate services, including physical therapy, occupational therapy, nutrition, materials, and respiratory care. This system also eliminated surgeons losing time moving between units.

The MGH disaster plan is modeled after the Hospital Emergency Incident Command System (HEICS) for disaster response. The Rhode Island nightclub fire required enormous operational and logistics management. To further complicate matters, most of the MGH patients were unidentified and lived in another state. Consequently, part of the response required interagency and intergovernmental



Washington Hospital Center's disaster preparedness aided in the quick treatment of Pentagon burn victims on September 11, 2001.

cooperation. Everyone had to cross state lines to do their jobs for the fire victims – insurers, state police and state agencies.

"Flexibility by senior leadership helped make Massachusetts General Hospital highly responsive," says Ms. Brush. "Our senior vice president for anesthesia and surgery, the senior vice president for patient care services/chief nurse and the hospital president managed the leadership in such a way that clinicians wanted for nothing during The Station nightclub disaster. This went beyond what we needed for patients. Food was provided 24 hours a day until the crisis had completely passed. They also made sure that people got to rest and received stress debriefings."

Massachusetts General Hospital also has a memorandum of understanding with the Department of Homeland Security and the U.S. Department of State as the sponsors of the International Medical Response Team. The team, including Ms. Brush, has most recently responded to the earthquake in Bam, Iran, and is readily prepared for future disasters worldwide.

Regardless of location, collaboration and effective communication are key to a successful disaster plan. "A resource-rich hospital environment, a strong disaster plan and flexible senior leadership are crucial to excellent disaster planning management," concludes Ms. Brush.

A Tribute to **Dr. Peter Safar**

supplement to *Critical Care Medicin*e entitled, "A Celebration of the Life of Peter J. Safar," will be published in February 2004. The supplement, sponsored by the Laerdal Foundation, is both a tribute to Dr. Peter Safar and a publication of the proceedings of the Second Annual Safar Symposium held in October 2003. The guest editors for this tribute are Drs. Ake Grenvik, Patrick M. Kochanek and John Schaefer.



Peter J. Safar, MD, FCCM 1924-2003

The first half of the supplement contains tributes and photos that highlight Dr. Safar's historic career, including his beginning as the pioneer of resuscitation invention, research and inspiration. The tribute also spans his work in controlled hypothermia for cerebral protection following hemorrhagic shock at the Baltimore City Hospital and the Safar Center for Resuscitation Research at the University of Pittsburgh. Remembrances are included from those lives Dr. Safar touched with his spirit and determination in the field of resuscitation, including colleagues, friends, admirers and students in the United States Army Medical Department and at the Safar Center for Resuscitation Research, all of whom remember him fondly. They recall his dedication to the importance of shared research, continued commitment to resuscitating every life that he could, sharing conversation and bottles of plum wine at a local Pittsburgh Chinese restaurant, his distinct Viennese accent and love of music, unparalleled humanity, ability to impact every person he met, and his overall integrity as a scientist and artist.

The second half of the supplement highlights the proceedings of the Second Annual Safar Symposium held in October 2003. The symposium included breakthroughs in resuscitation and advances in human simulation education. Both sections of the supplement are important pieces of the legacy that Dr. Safar left for everyone's enjoyment and education.

9

Utilizing *Information Systems* to Improve ICU Care



Although it is widely agreed that a properly designed and implemented medical information system would improve patient care, hospital departments, physician offices and other providers have hesitated to invest in such systems. Oftentimes, these data systems are incompatible with the organization's current medical record systems, leading to further difficulties in exchanging important patient information with local pharmacies, other hospital systems and physicians.

The Society of Critical Care Medicine (SCCM) continues its work in developing solutions to address these complex challenges.

Medication Errors on the Rise

10

The number of medication errors in U.S. hospitals increased by 82% in 2002, according to a report produced by U.S. Pharmacopeia. The report findings explain that hospital staff members detect many medication errors before patients receive treatment and that most of the errors did not have a serious impact on patients. According to the report, patients 65 and older were twice as likely to experience injury from a medication error than those in other age groups in 2002. In addition, about 10% of medication errors occurred because of errors in computerized order entry and approximately 17% occurred because hospital staff members failed to adhere to protocols.

Nancy Stonis, SCCM's director of program development and project coordinator for the Society's ICU Safety Reporting System (ICUSRS), states that "the large upsurge in medication errors found in the report could be due to better internal reporting procedures at the hospitals and a change in culture at those facilities that encourages the reporting of such errors. This type of change in reporting behavior is exactly what we need; identifying where the errors occur is the first step in designing systems to ensure they don't occur again."

Two years ago, the Society in partnership with The Johns Hopkins University School of Medicine, launched the innovative ICUSRS program to improve ICU safety. Its goal is to present an alternative method for reporting adverse events and near misses over the traditional mandatory incident report. The hypothesis was that people would feel safe and comfortable reporting to a system that was anonymous, confidential and focused on addressing system failures not blaming individuals.

Currently, 23 ICUs participate in the study, with over 1488 report submissions to date. Most of the incidents the ICUSRS Team analyzes involve two or more system factors, supporting previous evidence regarding the negative impact of complex work structures on safety. The finding that many medication events started outside the ICU, and that 65% of incidents reported were caused by poor communication, further illustrates the need for interactive and interconnected medical information systems. (See Page 5 in this issue of *Critical Connections* to learn more about ICUSRS and patient safety.)

Some patient safety groups advocate barcode systems that match the patient to the prescription to reduce medication errors. The Leapfrog Group, a coalition of large employers, supports the use of computerized physician order entry (CPOE) systems that allow providers to access patients' medical records and information about potential adverse drug events.

CPOE/CPOF Systems Help Reduce Errors

The Society's Coalition for Critical Care Excellence has placed an emphasis on the assumption that CPOE and computerized physician order fulfillment (CPOF) systems will reduce medical errors, improve quality of care and reduce costs in the ICU. Although preventable medical errors occur throughout the healthcare delivery system, it is generally accepted that the negative impact of errors is greatest in patients with life-threatening conditions. Because the most seriously ill patients are cared for in the ICU, it is reasonable to conclude that a properly designed and implemented CPOE/CPOF system in the ICU would result in error reduction and improved outcomes.

Significant efforts are underway throughout hospitals nationwide to develop and implement hospital-wide CPOE/CPOF systems. Understandably, these systems are primarily developed for the general outpatient and inpatient hospital areas. However, the ICU presents challenges unique to critical care. Consequently, a CPOE/CPOF system that can accommodate such complexities should be fully integrated in the ICU.

Two documents outlining CPOE and CPOF implementation in ICUs are available from the Society. Developed by the Coalition, "CPOE System Requirements for Intensive Care Unit Use" describes the essential elements for a CPOE system to be functional in the ICU. A subsequent document, "CPOF System Requirements for Intensive Care Unit Use," addresses ways to document the status, execution, and completion of all patient orders. Companies responsible for developing these systems and administrators considering purchasing and implementing CPOE systems will find these documents valuable. Access both documents (CPOE and CPOF) on SCCM's Web site, www.sccm.org.

In addition, the American College of Critical Care Medicine's (ACCM) theme to this year's Town Hall Meeting, held at SCCM's Congress, is "Computerized Physician Order Entry (CPOE): Achievements and Challenges." Learn from critical care colleagues about the successful implementation of and challenges associated with CPOE.

IOM Report Urges Creation of National Electronic System

While much emphasis has been placed on single systems such as CPOE and CPOF, the IOM reported in November 2003 that U.S. hospitals and other health providers should adopt a standardized, interactive, interconnected, electronic records system that would reduce medical errors. The first step to accomplishing the "health information infrastructure" recommended by IOM's 16-member panel requires health providers



David Julian Martin, CAE Chief Executive Officer/ Executive Vice President Society of Critical Care Medicine

to voluntarily begin using electronic medical records that contain access to patient information from all providers and alerts to possible adverse drug reactions.

The report recommends that use of such systems and participation in a nationwide system defined by government standards is necessary for providers to receive reimbursements from programs such as Medicare. The federal government would set technical standards for the exchange of medical information, clarify which types of "decision support" systems would assist health providers in treatment, create definitions of medical errors, and instruct hospitals on how to collect, analyze and distribute error data and solutions. Although the plan would give the federal government an unprecedented role in medicine, IOM's report describes the network as a "public-private partnership" that would lead to a large, "more seamless" structure for disease surveillance and patient treatment.

SCCM Hosts Technology Expert Roundtable

In the spirit of the IOM report and in further demonstration of SCCM's commitment to ICU technology solutions, the Society recently hosted a groundbreaking technology meeting. *Computers in the ICU: An Expert Roundtable* was an innovative, invitation-only meeting of physicians, nurses, hospital administrators, hospital information officers, and information systems vendors during which frank, open and challenging dialog occurred among all parties involved in the implementation of ICU information systems.

The three-day meeting was organized and led by SCCM Members Mitchell M. Levy MD, FCCM and William J. Sibbald, MD, FCCM, FRCPC, CHE and was made possible through the generous support of Clinicomp Intl., *Journal of Critical Care* (JCC) and Seimens.

The meeting allowed users and vendors of ICU computer systems to present their current uses, future needs and desired capabilities in an interactive setting. Highlighted topics included a retrospective of computers in the ICU, the impact of information technology on various ICU team members, relational databases, and computerized physician order entry (CPOE) systems. Expert speakers delivered information about their experiences and entertained questions, suggestions and criticism from the attendees.

The key messages from the conference included the value of computerization to research, patient safety and outcomes, staffing, and organization within the ICU. The results of the meeting will be published in the *Journal of Critical Care*. An executive summary is also planned for publication. In addition, a resource guide for SCCM members who may be considering computerizing their ICUs is planned for inclusion in an upcoming issue of *Critical Connections*.

The Society continues to advocate the integration of information technology into ICUs. These efforts will ultimately enhance patient care and serve as the basis for future SCCM policy development. Through interaction with government agencies, the results of these activities will be a health information infrastructure designed in part to ensure that patient safety efforts and the needs of ICU practitioners are fully met.



Photo courtesy of James Gathany; Centers for Disease Control and Prevention



Amy Guillet Agrawal, MD National Institutes of Health Bethesda, Maryland,

ince the initial isolation of West Nile virus (WNV) in 1937, the virus has caused outbreaks and sporadic cases of self-limited febrile illnesses, almost never causing meningitis or encephalitis. This changed in outbreaks that occurred in Romania in 1996, Russia in 1999, New York in 1999, and Israel in 2000, all of which had a much greater rate of encephalitis and death. The virus has evolved to a more neurotropic and virulent strain and is reemerging as a different pathogen. Still, most infected patients (80%) are asymptomatic, and only 1/150 develops severe neurologic illness.²

In a house-to-house serosurvey in New York following the 1999 outbreak, only 2.6% were IgG seropositive, and numbers were similar in Louisiana and Ohio (according to unpublished data from the CDC) after major outbreaks there in 2002.² The majority of the U.S. general population is still susceptible to WNV, and medical professionals, including those who practice critical care, continue to maintain their attentiveness in diagnosing and treating the disease.

Outbreaks in 2003 vs. 2002

As of January 7, 2004 there were 8977 cases of WNV in 45 states, of which 208 resulted in death. In 2002 the totals were 4156 human cases and 284 deaths.1 The epidemic continued to expand westward with Colorado being the hardest hit (2477 cases) and Nebraska and South Dakota a distant second and third. There are now locally acquired human cases in California, and animal surveillance indicates that the region may be next year's hot spot. Based on the lower death count, these case numbers likely represent an increased vigilance among clinicians and the public about testing for the disease.

New Clinical Information

Long-term follow-up on large numbers of patients is lacking, but following the 2002 outbreak in Louisiana, a neurologist followed 16 patients longitudinally for 8 months.³ Eight of them had encephalitis, five had meningitis and three (one with encephalitis) had acute flaccid paralysis. Movement disorders were seen in 15 of the 16 patients, and included tremor, myoclonus and Parkinsonian features. At the eightmonth follow-up, one patient had died and five of the seven living encephalitis patients and all of the meningitis patients had significantly improved. None of the three paralysis patients had improved — they were all still wheelchair-bound and not able to live independently. Tremor (often severe) persisted in five patients and Parkinsonism (e.g., bradykinesia, postural instability) persisted in five of the patients.³

"The majority of the U.S. general population is still susceptible to WNV, and medical professionals, including those who practice critical care, should continue to maintain their attentiveness in diagnosing and treating the disease."

In addition, over the last year several case reports and abstract presentations describing the magnetic resonance imaging (MRI) findings in West Nile encephalitis have been presented. Abnormalities are in the thalami, basal ganglia and cerebellum — findings which are similar to other flaviviruses and are distinct from those seen in Herpes simplex encephalitis.¹³

Diagnosis

By the time of presentation to a clinician, most patients have already cleared the virus from the blood and the cerebrospinal fluid (CSF) and are making antibody. As a result, the diagnosis is usually made with a positive immunoglobulin M (IgM) in either serum or CSF, which is more sensitive. The antibody cross-reacts with other flaviviruses, thus IgM for Saint Louis encephalitis virus is often also positive, and confirmatory testing with plaque reduction neutralization assays is required. A notable exception to this scenario is in the immunocompromised patient. Cancer, organ and bone marrow transplant patients have a more prolonged prodrome, remain PCR positive in CSF and blood longer, have difficulty mounting an antibody response and have a worse outcome. In these patients, a West Nile PCR should be sent as well as serology.

During the summer and fall months, West Nile has surpassed herpes simplex virus (HSV) as the most common cause of viral encephalitis, and should always be sought as a diagnosis. For meningitis, enteroviral and bacterial cases still occur more commonly, but West Nile IgM should also be sent in these patients if gram stains are unrevealing. For patents with fever only, the diagnosis is extremely unlikely to be WNV and these patients almost uniformly do well unless they are immunocompromised. Thus, testing for WNV is unnecessary, except for epidemiologic purposes.

Although the screening of pooled blood products in 2002 for WNV nucleic acid greatly reduced the number of transfused viremic units, there were two cases of transfusion transmitted WNV that came from donors whose level of viremia was below the sensitivity threshold of the test. Upon retesting of their individual retained samples, both were then found to be positive.⁴ Blood product transfusion within one month should still be considered a risk factor for the development of disease.

Developing a Vaccine

Phase one testing of a promising live vaccine (ChimeriVax-WestNile,

Acambis) for humans began in late 2003, which aims for the safety, tolerability and immunogenicity in normal volunteers. If these trials are successful, the question may still remain open as to its safety in target groups such as the elderly and immunocompromised. The West Nile vaccine is not expected to become commercially available for at least three years.

Identifying Therapies

Several compounds for treating patients infected with the West Nile virus have been considered. One is interferon alpha, which is active in vitro, and has not been tested in animal models of WNV. A large, double-blind placebo controlled trial of this agent against closely related Japanese encephalitis virus showed the treatment to have no benefit over placebo.⁵ A human trial is ongoing.⁶

Case reports described anecdotal success in the use of passive immunization to treat West Nile encephalitis.7,8 The compound used was Israeli IVIG, which contains high levels of specific antibody against WNV. The virus circulating in North America has a >99% sequence homology to one isolated in Israel, and thus likely came from there to New York in 1999.9.10 Several animal models have subsequently documented a mortality benefit if specific antibody is given early after the infectious inoculum.^{11,12} American IVIG contains no detectable anti-WNV antibody, and does not work any better than saline in animal models.

A multicenter national Institutes of Health (NIH)-sponsored trial is underway to look at the safety and preliminary indications of efficacy of Israeli IVIG vs. American IVIG vs. saline placebo. For information on participating sites, visit www.casg.uab. edu. To view the inclusion and exclusion criteria, visit www.clinicaltrials.gov, and search for West Nile.

References are available at SCCM's Web site, www.sccm.org/publications.

SARS as a Paradigm of Emerging Infections



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"While the future impact of SARS is hard to predict, it is clear that the world community will be faced with other emerging infections as time goes on...[and] the intensive care unit will continue to be intricately involved in the care of patients with such infections."



Patrick Stockton of the Special Pathogens Branch is examining a T-25 flask used in the SARS virus isolation. (2003)

Photo courtesy of Centers for Disease Control and Prevention (CDC).

icrobial threats continue to emerge, reemerge, and persist." These words are found in an Institute of Medicine (IOM) report entitled Microbial Threats to Health.¹ The report, authored by a committee of eminent scientists, focused specifically on the emerging microbial threats to public health. It was released within days of the World Health Organization's (WHO) global alert on an atypical pneumonia that would eventually be known as severe acute respiratory syndrome, or SARS.² The irony of the timing is lost on few.

The human race has always had a tenuous relationship with microbes. While usually this relationship is balanced, history shows that when there is disequilibrium, the consequences to society can be considerable. Historical examples include the bubonic plaque (Black Death) of the Middle Ages, or the influenza pandemic of 1918. A recent example of similar impact is human immunodeficiency virus (HIV). While these examples are notable because of the number of people affected, they represent only a small fraction of emerging infections.

Emerging pathogens are generally defined as "infections that have newly appeared in a population or have existed but are rapidly increasing in incidence or geographic range."³ Numerous examples can be shown in the last several decades. One of the most striking in the last few years is the emergence of the SARS coronavirus.

SARS is a constellation of fever, cough and other respiratory symptoms caused by infection with the SARS coronavirus. This syndrome can be associated with acute respiratory distress syndrome (ARDS) and severe hypoxia, and attends a mortality rate of 9.6%. From November 2002 through June 2003, a total of 8098 cases of SARS occurred worldwide, resulting in 774 deaths.⁴ While the future impact of SARS is hard to predict, it is clear that the world community will be faced with other emerging infections as time goes on. It is also clear, as evidenced in the SARS outbreak, that the intensive care unit will continue to be intricately involved in the care of patients with such infections. It is therefore useful to employ SARS as one paradigm to discuss the threat of emerging infections and their impact on the critical care environment.

Emerging infections appear from a variety of sources. These include zoonotic transmission of the infectious agent from an animal reservoir to humans-SARS appears to fit this model. Other mechanisms of emerging diseases include genomic evolution of the pathogen in response to external stimuli, both natural and man-made. The emerging antibiotic resistance seen across the world and in our intensive care units represents this phenomenon. Changes in the host also predispose to new infections, as is evident by the unique pathogens that cause disease in the immunosuppressed host. Lastly, intentional release of infectious agents, natural or modified, can be considered as emerging pathogens. Although each emerging infection is unique, there are common themes involved in the emergence of new pathogens, including SARS.

A number of viruses are endemic in animals and only occasionally cause diseases in humans. Two notable examples receiving media attention in the last year are Ebola and monkeypox. These viruses, when they infect humans, have similar structures as those found in the animal reservoir. Similarities in receptors allow the virus to infect more than one species. One example is influenza, where the virus has multiple natural hosts including birds and other mammals. Sialic acid, the molecule influenza uses to facilitate entry into host cells, differs slightly across species. This dictates the usual species tropism seen among influenza viruses.5 There is enough similarity in this molecule, however, to allow the virus to cross between species.

Occasionally, viruses establish new strains in different species. The

prototypical example of this is HIV. The HIV-1 genome is closely related to the simian immunodeficiency virus (SIV) capable of infecting the chimpanzee, while HIV-2 is closely related to the SIV affecting the sooty mangabey.^{6,7} While closely related, the human viruses are genetically distinct implying that the differences are necessary, or evolutionarily optimized, to infect humans.

It is unclear which model of zoonotic infections SARS coronavirus will fit. A similar coronavirus has been isolated in Himalayan palm civets and raccoon dogs found in a market in southern China.⁸ However, these viruses are not identical to those found in humans with SARS. The SARS coronavirus has a 29 base pair deletion when compared to the animal virus.⁸ Early evidence suggests this deletion merges two open reading frames into one. The functional consequence of this deletion isn't clear, though it maybe necessary for human infection.

There are multiple factors that may lead to the emergence of new infectious agents. Social and economic factors contribute to the emergence of some microbes and have been suggested for SARS. The capture and slaughter of wild animals in southern China may have been the initial source of SARS. Early reports suggested that many of the early cases of SARS were seen in butchers and other restaurant workers. It has subsequently been shown that 40% of wild animal traders in the Guangdong province of China have antibody to the SARS coronavirus.8 The animal traders tested did not have any history suggestive of SARS This finding suggests that SARS transmission and infection may occur much more frequently than appreciated. The same may be true of other zoonotic emerging infections.

One should not think that this situation is unique to animal markets in China. Variant Creutzfeldt-Jakob Disease (Mad Cow Disease) is a prion disease that can be circulated in cattle. It has been found in the United Kingdom, Canada, and most recently in Washington state and has potential to threaten the beef supply to many Western countries. It is only through diligent quarantine, destruction of infected cattle and modification of feeding practices that this disease has not spread further.

Global commerce and international travel contribute to emergence of new infections by transporting microbes, hosts or vectors from endemic areas to previously unexposed areas. A notable example is West Nile virus, which is endemic in parts of Africa and the Middle East. The first documented incursion of this virus in the United States occurred in New York in 1999. Since its introduction, there has been a progressive spread of West Nile virus across the United States with over 10,000 cases reported to the Centers for Disease Control and Prevention (CDC). Other examples include the monkeypox outbreak in central United States in 2003 that was associated with the importation of the Giant Gambian rat, and subsequent infection of prairie dogs, all part of the exotic pet industry.9

International travel can be responsible for rapid dissemination of microbes to multiple countries. After the initial cases of SARS in southern China, there was rapid dissemination by air travel to over 25 countries. Several of these areas experienced significant local transmission of the virus. Another example of international travel contributing to dissemination of microbes would be the cases of malaria reported near airports in patients that never traveled. These occurrences presumably result from mosquitoes taking a blood meal from recent international travelers.

Important lessons learned during the SARS situation can be applied to future emerging infectious diseases. The rapid dissemination of information during the SARS outbreak was unprecedented. For example, less than one month after the World Health Organization (WHO) released the first global alert for SARS, the sequence of this new coronavirus was published in a peer-reviewed journal.¹⁰ This quick distribution of information is a testament to worldwide collaborative efforts. expedited manuscript submission and review, editorial prioritization, and electronic publishing by the peer-reviewed journals.

Researchers have made tremendous strides in developing diagnostic tests and establishing a candidate vaccine that is protective in the animal model of the SARS infection.¹¹ The pace of basic SARS research has been unprecedented.

Clinical research has not enjoyed the same level of achievement, however. Early in the outbreak of SARS, thousands of people were treated with ribavirin. Even though there was no experimental evidence to support these practices, the initial reports lauded ribavirin for its efficacy. Later it was demonstrated there was no in-vitro activity of ribavirin against the SARS coronavirus. While not efficacious for the treatment of SARS, ribavirin did have significant side effects. It has been shown that 61% of patients treated with ribavirin had hemolytic anemia, with a mean drop in hemoglobin of 2.8 g/dL.¹²

A similar scenario may be true of corticosteroids. To date, there is no clinical study to support their use in treating SARS. Recently, it has been revealed that a significant proportion of those treated with corticosteroids have developed avascular necrosis of the femoral head or other complications from this therapy. Definitive proof of corticosteroids utility is difficult to illustrate, however, as in-vitro studies would not interrogate the presumed mechanism of action and animal models lack the severity of lung disease seen in humans.

Clinical research in the face of emerging infectious diseases is very difficult, though critically important. Structured research protocols evaluating the natural history of these infections will provide the best means for understanding the pathophysiology of the disease. While there may be a need to try unproven therapies for these infections, doing so in a structured treatment protocol to evaluate the efficacy of these medications ensures that patients aren't given medication with potentially serious side effects. Implementing clinical research in a relatively short time frame is difficult, and doing so in the face of an epidemic can be impossible. However, reviewing the SARS outbreak emphasizes this need.

It has been said, "Experience is a hard teacher. She gives the test first and the lessons afterwards."¹³ Learning the lessons that the SARS outbreak has to teach is critically important. Such evaluations will be applicable to the larger theme of emerging infectious diseases and will continue to be a part of the practice of critical care.

References are available at SCCM's Web site, www.sccm.org/publications.



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Annual Report to Members and Donors



David Julian Martin, CAE Chief Executive Officer/ Executive Vice President Society of Critical Care Medicine

ith 2003 behind us, it's my pleasure to provide you with this report of the Society of Critical Care Medicine's (SCCM) activities. Whether you are a longtime SCCM member, a new member, a contributor to the Society's Foundation, or considering joining SCCM, I think you will concur that 2003 was our best year yet.

Our goals for 2003 were to: enhance and expand offerings and distribution of SCCM educational programs; promote access to compassionate, patient-centered care delivered by a multiprofessional, intensivist-directed team; and develop ICU patient safety initiatives that will reduce medical errors and lessen variability in delivery of care.

The year began with another record-breaking Annual Critical Care Congress. It was not only a year for top attendance – program content reached new heights. This success set the stage for an outstanding accomplishment at the Society's first ever Summit on ICU Quality and Cost, followed by a successful ESICM jointly-sponsored Summer Conference on Hemodynamic Monitoring and overflowing attendance at the Society's annual Multidisciplinary Critical Care Review Course.

While these programs surpassed expectations programmatically as well as in member participation, the large crowds did present operational challenges. As a result, SCCM staff have taken steps to ensure that meeting facilities in 2004 can accommodate all who wish to participate. New programs in 2004 include meetings such as the International Consensus Conference in Intensive Care Medicine: The Management of Acute Pancreatitis; the Summer Conference in Intensive Care Medicine – Mechanical Ventilation: Current Trends and Future Directions; and Pharmacotherapy in Critical Illness: Evidence and Controversy.

The Society's publishing operations also experienced a number of successes in 2003. In fact, SCCM was pleased to be the first healthcare organization to produce a text exclusively for medical professionals facing natural and man-made disasters. *Fundamentals of Disaster Management* was enthusiastically received by SCCM members and the public. Complimentary copies were distributed to key government agencies and portions of the publication will soon be posted on the SCCM Web site to assist practitioners during times of crisis.

In addition, SCCM released the monograph, Sepsis: Pathophysiologic Insights, and the Fifth Edition of the popular Self-Assessment in Multidisciplinary Critical Care. A monograph and interactive CD-ROM from the successful Summit on ICU Quality and Cost along with the only book written expressly about coding for the ICU, *Coding and Billing for Critical Care*, rounded out a year of record publication activity with overall publication sales up 25% over the prior year.

These activities were in addition to another year of thought-provoking articles in our flagship journal, *Critical Care Medicine* (CCM), and its sister publication, *Pediatric Critical Care Medicine* (PCCM). Both journals implemented new features in 2003. *Critical Care Medicine* launched a new bi-monthly section entitled "Concise Definitive Reviews in Critical Care Medicine," with R. Phillip Dellinger, MD, FCCM as editor. In addition to the monthly issues of CCM, eight supplement issues were published in 2003, including meeting proceedings and general topics of interest such as ethics and wound healing.

Pediatric Critical Care Medicine began offering continuing education credit in each issue beginning with the January 2003 issue. In addition to translating abstracts into Chinese, French, Japanese, and Spanish, Italian was added as well. The most noteworthy development for PCCM is that beginning with the January 2004 issue, the journal transitioned from a quarterly publication to a bi-monthly publication.

The Society's bi-monthly news magazine, *Critical Connections*, also experienced a banner year, with cutting-edge themed issues, the addition of a "Vital News" section aimed at providing the latest events, studies and technologies in critical care, and enhanced design elements. Furthermore, the magazine continues to feature Success stories, which highlight organizations that have successfully implemented the multidisciplinary team model in their ICUs, and Coding Corner, an essential resource for practitioners coding critical care services.

In 2004, members can anticipate the release of three sister publications detailing the results of the Society's surveys on ICU Benchmarking, including ICU Operations, Salary and Benefits, and Contracts and Job Descriptions. In addition, look for the first release of the Critical Care Assessment of Resource Efficiency and Safety (CCARES) program. This program will integrate quality and outcome measures with patient safety concepts to assist ICUs in assessing their overall performance.

The Society along with Joint Commission Resources, a subsidiary of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), has produced an important new book entitled, *Improving Care in the ICU*. The Joint Commission and SCCM collaborated to address the applicability of hospital- and disease-specific standards to the ICU, focusing on patient care. The book includes valuable information about various facets of the ICU and solutions to the multitude of challenges that occur in and around the ICU. Additional milestones include a dramatic increase in participation in the Fundamental Critical Care Support (FCCS) course (trainees increased by 50%). The course continues to gain exposure throughout the United States and internationally.

Through the active efforts of volunteers, SCCM continues to reach critical care professionals and the public through informational brochures and updates. The Society produced seven ICU waiting room brochures, video and public radio news releases on important public health issues, and a comprehensive tips brochure, *Improving Your ICU: Tips for Better Care.* As a result, many of the Society's efforts and a number of SCCM members received significant press coverage. The Society also continues to be involved with the Surviving Sepsis Campaign.

On the partnership front, SCCM continues to build bridges with other organizations in developing collaborative relationships. Along with the American Association of Critical-Care Nurses (AACN), American College of Chest Physicians (ACCP), and the American Thoracic Society (ATS), the Society continues to identify solutions related to the critical care workforce. In January 2003, the presidents of each organization presented the Framing Options for Critical Care in the United States (FOCCUS) Work Group's paper that reviews the delivery of healthcare within the United States and provides recommendations to redefine how that care is delivered using the current personnel. From the FOCCUS paper, SCCM supported The Critical Care Medicine Crisis: Call for Federal Action white paper sent to the U.S. Department of Health and Human Services (HHS)-Health Resources and Services Administration.

The Society also enjoys a growing relationship with Joint Commission Resources and has a member sitting at the table with the American College of Physicians Council of Subspecialties Societies.

In addition, HHS joined with key national leaders and practitioners from the nation's transplantation and hospital communities in April 2003 to launch the Organ Donation Collaborative. The Society has donated booth space at the 2004 Critical Care Congress to this effort.

The Society continues to collaborate with the American Thoracic Society, the European Respiratory Society (ERS), the European Society of Intensive Care Medicine (ESICM), and Société de Réanimation de Langue Française (SRLF) to bring current clinical information to the international community by holding the International Consensus Conference in Intensive Care Medicine. The 2004 conference will be held in Washington, D.C., April 15-16, and will focus on the Management of Acute Pancreatitis.



In addition, SCCM and ESICM will again jointly sponsor the Summer Conference in Intensive Care Medicine. This year's topic is Mechanical Ventilation: Current Trends and Future Directions and the conference will be held June 25-27, 2004 in New York City.

The Society's advocacy efforts include the continued work of the Critical Care Work Group (CCWG). This multi-organizational group continues to review and address reimbursement issues for the critical care provider. In April 2003, CCWG met with the Centers for Medicare and Medicaid Services (CMS) to discuss inconsistencies in the Carrier Manual related to reimbursement at the local carrier levels and refinement of the definition of critical care. The group is awaiting a response and/or release of the revised manual.

Furthermore, SCCM continues to work with the American Medical Association (AMA) on its RBRVS Update Committee (RUC), Current Procedural Terminology (CPT), and through the AMA House of Delegates. The Society has published Coding and Billing for Critical Care, and recently collaborated with ATS and ACCP to help pass a resolution that addresses the pending physician shortage and its implications for critical care.

Significant efforts related to Research Ethics have been initiated over the past year, especially in light of the issues surrounding the ARDSNet Trial. The Society's Council addressed the issue after reviewing a background paper prepared by a combined work group from the Research and Ethics Committees. These efforts were followed by discussions with Joint Leadership, and SCCM representatives attended two national conferences on the subject.

Because of these many successes, SCCM membership grew to over 11,000, up from approximately 9,000 just three years prior. In addition, gross operating revenues reached a record high of \$11 million, and net revenues exceeded budgetary goals by nearly 100%, permitting the Society to increase its investment in future activities. The Foundation, only in its second year of activity, doubled its fundraising goals. Those funds will be used specifically as set forth by the generous donors to expand programming in designated areas.

In all, 2003 was an exceptionally successful year for SCCM. The Society continued to fulfill its mission to secure the highest quality care for all critically ill patients. New programs flourished, providing the Society with a stable financial base to improve and expand its activities in 2004 and beyond. Through increased membership, active participation in SCCM programs, and the generous support of donors and program sponsors, we were able to greatly surpass our expectations and make significant advances toward our envisioned future of a health system in which all critically ill and injured persons obtain optimum care in an optimum setting, resulting in improved outcomes.

Thank you to each and everyone one of you who contributed to SCCM's success through the commitment of your time, participation and generous support. You have helped the Society achieve its goals in 2003 and have paved the way for improved programs and products in 2004. Nurses, pharmacists, respiratory therapists, physicians, and other ICU team members all working together to make significant advances in care for the critically ill ... this is what SCCM is about. We're so pleased to have you as part of our team!

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David Julian Martin, CAE Chief Executive Officer/Executive Vice President Society of Critical Care Medicine

Critical Care Education and Research Foundation

The Society of Critical Care Medicine's (SCCM) Critical Care Education and Research Foundation (CCERF) experienced a promising 2003 fiscal year. The Foundation helps sustain the Society by securing funding for critical care research and education, as well as providing valuable information to the public by securing contributions from individuals, foundations and corporations. Because of these gifts, the Society continues its efforts in advancing the critical care profession, serving its members and promoting patient safety.

Through several membership appeals and a successful campaign at the 32nd Critical Care Congress, the CCERF received 467 gifts in 2003. These gifts were designated as follows:

- Research: Designated for SCCM research programs.
- Unrestricted: Funds will support the general mission and programs of the Society.
- Patient Safety Research Grant: Restricted to fund a new Patient Safety Research Grant.*
- FCCS: Restricted to provide Fundamental Critical Care Support (FCCS) course licenses to organizations in developing or impoverished countries.*
- ACCM Guidelines and Practice Parameters: Restricted to the Society's American College of Critical Care Medicine (ACCM) for the development of a new guideline or practice parameter.*

• Other: Designated for the development of new patient and family educational materials, the Society's Registered Nurse Specialty Section, and to sponsor a fellow's one-year membership to SCCM.





Help make these programs happen. Only \$55,000 is needed to fund a new Patient Safety Research Grant, \$1,500 for an FCCS License, and \$19,000 for a new ACCM Guideline and Practice Parameter.

The Society extends its appreciation to the following members and friends for their generosity in supporting the CCERF

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To the many members who contributed using membership dues forms, please know that your continued support is greatly appreciated. To make a donation to the CCERF, please contact Pat Langford at plangford@sccm.org or (847) 827-7157.

Joseph M. Civetta, MD, FCCM to Receive Lifetime Achievement Award

Joseph M. Civetta, MD, FCCM, will be honored with the Society of Critical Care Medicine's (SCCM) Lifetime Achievement Award during the 33rd Critical Care Congress for his numerous scientific and clinical advances in critical care medicine, as well as his extraordinary organizational vision and leadership.

Dr. Civetta joined the Society of Critical Care Medicine in 1972. "At that time there was a technological and knowledge explosion in critical care. It was the perfect opportunity for a young intensivist," he says. "I was already writing papers and presenting research – because everything was so exciting. The size of the organization allowed the active, young members a chance to be involved. In 1981, at the age of 43, I became president. Now, as then, SCCM has remained unique by encouraging and supporting a youthful leadership."

Dr. Civetta's position as president enabled him to reach international critical care professionals. "I was fortunate to be president of SCCM in a World Congress year. I became the *de facto* president of the 1981 World Congress," explains Dr. Civetta. "It was a memorable event – I was able to meet all the critical leaders from around the world."

During his presidential year, SCCM's by-laws changed, shifting the principal focus of the organization. The new by-laws encouraged young critical care professionals to join early in their careers, greatly expanding membership. "That was our primary goal from 1979 to 1983," says Dr. Civetta. "SCCM started with 20 members and now has a membership of more than 11,000."

Originally a small "club" of renowned and established critical care practitioners, the Society grew into an organization that is now well known for providing education and learning. The annual meeting functions as a primary educational experience and the presentation of papers and scientific sessions helps shape young investigators into the critical care leaders of the future.

Dr. Civetta still remains active in the Society, more than 30 years after joining.

Scientific Contributions

Dr. Civetta was nominated for the Lifetime Achievement Award due to his continuous efforts to improving quality of care delivered to the critically ill. "I am proud to have played a role in instituting improvements in clinical practice," says Dr. Civetta. "Much of what I have done in the past 35 years was process oriented. I have been able to take existing physiologic principles and modify them for clinical practice. "Thirty years ago, I helped in the initial application of cardiovascular monitoring in critical care," comments Dr. Civetta. "My group was one of the first to use pulmonary artery catheters in surgical patients rather than solely in cardiology patients. I was co-author of the first pulmonary artery catheter paper outside the cardiology literature, which examined critical care's ability to better manage patients and discern what was occurring. That trend in collecting information is continuing today."

Dr. Civetta was one of a group (including Robert Kirby, MD and John Downs, MD, FCCM) that changed the approach to ventilatory support. Their changes from the standard approach – Intermittent Mandatory Ventilation, High Level Positive End Expiratory Pressure and Invasive Cardiovascular monitoring – opened the door to alternatives in respiratory failure treatment. Since then, the development and application of new approaches from around the world decreased the mortality rate for acute respiratory distress syndrome (ARDS) from 90% to 30%.

Finally, Dr. Civetta worked with the University of Miami intensivists, especially Orlando Kirton, MD, FCCM, and collaborated with Michael Banner, PhD, RRT at the University of Florida in the 1990s utilizing bedside computerized monitors for measuring patient breathing and challenged previous concepts of weaning patients from ventilators.

"I am proud to have played a role in instituting improvements in clinical practice."

Another area of Dr. Civetta's achievements was in device-related nosocomial infections. "We combined diagnosis and technology to better care for patients requiring catheters," Dr. Civetta explains. "We developed guidelines and rules that could be applied to both diminish the cost of routine device changing and to increase safety with decreased infection rates."

While at Massachusetts General Hospital, Dr. Civetta and David Cullen, MD developed the therapeutic intervention scoring system to predict resource utilization and outcomes, based on the number and complexity of bedside treatments.

Dr. Civetta's group at the University of Miami was instrumental in adopting the use of the military antishock trouser, or MAST, to stabilize automobile accident patients while in transport. Although MAST is not widely used today, it was a crucial development



Joseph M. Civetta, MD, FCCM

for better managing trauma patients and remains useful in treating pelvic fractures and coagulopathic intra-abdominal bleeding.

Currently, Dr. Civetta is researching ways to prevent multiple organ system dysfunction. "Because multiple organ system dysfunction appears to be related to ischemia reperfusion injury, we are giving medications to cardiac surgery patients before and during their operations to see if we can alter their outcomes," he explains.

Dr. Civetta and his wife, Judith Hudson-Civetta, MSN, have collaborated on numerous scientific and review articles. She has been his research associate for the last 20 years. "If you read any of our papers, you can be sure that the data is valid because my wife collected it," says Dr. Civetta anecdotally.

Dr. Civetta is honored to receive SCCM's Lifetime Achievement Award. "This lifetime achievement award is an award I will cherish above all others. The Society helped me progress from a novice to leadership roles. The greatest pleasure is to be 'in charge' which meant that I was surrounded by extraordinary people, the SCCM Council," he concludes.

Dr. Civetta is professor of surgery and the vice-chairman of the department of surgery at the University of Connecticut Health Center in Farmington. He is also program director of the University of Connecticut's integrated general surgery residency. A prolific researcher, Dr. Civetta is author or co-author of more than 350 publications including peer-reviewed research, abstracts, book chapters, and books. He is the recipient of nearly 30 awards and honors.

Dr. Civetta received a bachelor's degree from the College of the Holy Cross in Worcester, Massachusetts, and a medical degree from the Boston University School of Medicine. He completed a surgical residency at Massachusetts General Hospital in Boston. In addition to the Society of Critical Care Medicine, Dr. Civetta is a member of the American Academy of Pain Medicine, the American College of Surgeons, the American Surgical Association, the Association of Program Directors in Surgery, the New England Surgical Society and the Society of University Surgeons.



WASHINGTON UPDATE

Congress Passes Prescription Drug Bill, Including Benefits to Physicians

In a very close vote, with last minute arm-twisting by President Bush himself, the House passed the prescription bill by a margin of 220 to 215 on November 20, 2003 and the Senate by 55 to 44 on November 23. The Medicare prescription drug legislation includes a number of provisions designed to benefit physicians. The Society fully supported the legislation because of the provisions pertaining to physicians and signed numerous letters of support during the months this legislation was pending before Congress.

The legislation benefits physicians in the following ways:

• Forestalls a 4.5% decrease in Medicare physician reimbursement that was scheduled to go into effect January 1, 2004. Instead, the legislation provides for a modest 1.5% increase which began on January 1, 2004 and another 1.5% increase for 2005. In addition, the formula that the Centers for Medicare and Medicaid Services (CMS) uses to calculate the Medicare update factor each year will be changed to hopefully alleviate additional decreases beyond 2005.

The legislation provides significant improvement in the regulatory system applicable to providers. For example, new requirements will not be permitted to be included in a final rule, unless the public has had an opportunity to comment on the substance of the proposed changes. In addition, retroactive application of new regulations and policies will be prohibited. The legislation also protects providers who follow written guidance from CMS or a contractor from the imposition of sanctions, if that guidance is found to be inaccurate or erroneous.

A new competitive process for contracting for Medicare administrative functions (such as claims processing and payment) will be created. Medicare contractors will be prohibited from using attendance records from educational activities in selecting providers for audit or prepayment review.

• The Secretary of the U.S. Department of Health and Human Services (HHS) will be required to develop a provider enrollment process within six months after enactment of the legislation. This process will include deadlines for CMS to act on applications, and hearing rights in cases in which enrollment is denied or not renewed. Before provider enrollment forms are changed, CMS will be required to consult with providers and suppliers. The Secretary will also create a process for providers to correct minor errors in claims that have been submitted.

- When legal issues cannot be resolved administratively, access to judicial review will be expedited; this expedited review will be mandatory in certain circumstances. And in cases of hardship, providers who owe overpayments to the government will be given an extended period of time to repay those funds.
- The bill also requires the Secretary of HHS to develop a strategy for improving communications with beneficiaries, providers and contractors. Medicare contractors will be required to provide clear, concise and accurate responses to written inquiries within 45 days of receipt.

Other Developments in Medicare Payment Policy

Apart from the encouraging change to the Physician Pay Schedule noted above, a number of other changes to Medicare Payment policy resulted from administrative actions.

- CMS, HHS issued a final rule revising the payment policies under the Physician Fee Schedule for calendar year 2004. Comments on the physician self-referral designated health services additions and deletions and the interim work Relative Value Units (RVUs) for selected procedure codes were collected in January. (68 Fed. Reg. 63195)
- CMS, HHS issued a final rule with comment period revising the Medicare Hospital Outpatient Prospective Payment System and calendar year 2004 payment rates. Comments on the ambulatory payment classification assignments of HCPCS codes identified with "new interim" condition codes were also collected in January. (68 Fed. Reg. 63397)
- CMS, HHS issued a final rule creating a new process to allow certain Medicare beneficiaries to challenge National Coverage Determinations and Local Coverage Determinations. (68 Fed. Reg. 63692)

If you wish to learn more on any aspect of the above rules, please contact Eric Chandler, manager of professional affairs, at (847) 827-6866 or echandler@sccm.org.

Hearing on development of 'Seamless' Medical Records for Military Personnel

Oversight and Investigations The Subcommittee of the House Veterans' Affairs Committee held a hearing November 19, 2003 on progress being made by the Department of Defense and the Veterans' Affairs Department regarding the sharing of medical information and the development of a seamless medical record. Δ

Rationales Now Available for ABIM's **SEP Modules**

The American Board of Internal Medicine (ABIM) has partnered with professional societies to provide rationales for the Self-Evaluation Process (SEP) modules used in the recertification process. The Society of Critical Care Medicine (SCCM) formed a committee, co-chaired by Antoinette Spevetz, MD, FCCM, and Donald B. Chalfin, MD, MS, FCCM, to develop the educational content for the questions. The aim of this educational tool is to help critical care professionals complete the SEP modules in a more time efficient manner.

The questions will aid critical care practitioners in the recertification process. Because ABIM mandates that the answers to the questions not be divulged, the booklet includes a discussion of the topic that provides the knowledge necessary for professionals to answer the question. The ABIM plans to release an additional critical care booklet in 2005.

The rationales for the two critical care modules are available on SCCM's Web site at www.sccm.org. The Society welcomes your comments on the general format of the questions and/or specific questions. Please email your feedback to Christina Cottini at ccottini@sccm.org.

The Society hopes this tool will assist you in the recertification process. When the other critical care booklet becomes available in 2005, the Society aims to provide the same service. As other societies develop rationales for their specialty questions, SCCM will provide the links to assist you with other SEP modules you choose to complete. Δ

New Book on Improving ICU Care

The Society of Critical Care Medicine (SCCM) and Joint Commission Resources (a subsidiary of Joint Commission on Accreditation of Healthcare Organizations [JCAHO]) have come together to produce an important new book entitled, Improving Care in the ICU. The Joint Commission and SCCM collaborated to address the applicability of hospital- and disease-specific standards to the intensive care unit (ICU), focusing on patient care. This collaboration signifies each organization's dedication to improving healthcare standards. The book includes information about various facets of the ICU, offering valuable solutions to the multitude of challenges that occur in and around the ICU by utilizing intensivist-directed models for delivering care to critically ill patients. In addition, the book discusses the high risk of adverse events, levels of care, the multidisciplinary approach, staffingissues, relevant JCAHO standards and requirements, and telemedicine in the ICU.

This book is available at a discount for all SCCM members. Please contact SCCM Customer Service to place your order at (847) 827-6888. Δ



SCCM-supported Study Published in The New **England Journal of** Medicine; Results to Be **Presented at 2004 Congress**



he Society of Critical Care Medicine (SCCM) recently supported a study spearheaded by SCCM Member Volker Wenzel, MD, along with additional investigators, that examined vasopressin as an alternative clinical therapy to epinephrine for vasopressor therapy during cardiopulmonary resuscitation. The results of the study were published in an article entitled, "A Comparison of Vasopressin and Epinephrine for Out-of-Hospital Cardiopulmonary Resuscitation," in the January 8, 2004 issue (Vol. 350, No. 2) of The New England Journal of Medicine (NJEM).

Major findings of the study led to the conclusion that "vasopressin, as compared with epinephrine, improved the rates of survival to hospital admission and discharge, but only among patients with asystolic cardiac arrest. There was no advantage to vasopressin therapy in patients with ventricular fibrillation or pulseless electrical activity," according to the Editor's Summary of the NEJM article. The summary goes on to explain, "If confirmed, these findings will further refine approaches to vasopressor therapy in patients with cardiac arrest and will lead to changes in the recommendations for cardiopulmonary resuscitation."

In addition to the study results appearing in The New England Journal of Medicine, the Society of Critical Care Medicine will present a Late-breaking Session on the topic during its 33rd Critical Care Congress in Orlando, Florida. Valuable to all members of the critical care team, the study's findings will be presented by Dr. Wenzel on February 22, 2004.

Tell Us....

Your comments on editorial coverage and story ideas for Critical Connections are always welcome. All articles are subject to editing for style, space, and relevance. Please include your name, title, organization, phone number, and email address with your submission. Submit your correspondence to:

Mail: Managing Editor, Critical Connections, Society of Critical Care Medicine, 701 Lee Street, Ste. 200, Des Plaines, IL 60016 Email: criticalconnections@sccm.org

Fax: (847) 827-7291



HEALTHCARE IMPROVEMENT

Calls To Action

Innovations in **Critical Care Delivery**

Four 90-minute conference calls with leading experts on improving the efficiency and effectiveness of the Intensive Care Unit

This Calls to Action series will focus on innovative changes that can result in new, dramatic breakthrough performance with infections and other complications of critical care delivery. Through four 90-minute calls with leading experts in the field, you and members of your organization will be able to understand and implement changes to improve care delivery in the Intensive Care Unit, including sepsis diagnosis and treatment, use of ventilator bundling, financial modeling and more.

Thursday, April 8th, 2:00-3:30 PM ET

Call 1: Providing Systematic Round-the-Clock ICU Care Thomas G. Rainey, MD, FCCM and Peter Pronovost, MD, PhD

Thursday, April 15th, 2:00-3:30 PM ET

Call 2: Surviving Sepsis Roger Resar, MD and Peter Pronovost, MD, PhD

Thursday, April 22nd, 2:00-3:30 PM ET

Call 3: Critical Care Redesign: A Potpourri of Essentials Terry P. Clemmer, MD, FCCM and Vicki Jensen Spuhler, RN, MS, CCRN

Thursday, April 29th, 2:00-3:30 PM ET

Call 4: The Business Case for **Redesigning ICU Care** Thomas G. Rainey, MD, FCCM

Fee:

\$1350 for the series of four calls includes: one telephone connection, one set of handout materials and unlimited participant attendance at your site.

To Register: Please visit our website at www.ihi.org or call our vendor, KRM at 800-775-7654

Section and Chapter news

The many sections and chapters of the Society of Critical Care Medicine provide a vehicle for critical care practitioners to network with critical care professionals who have similar interests or are involved in facilities in the same area. The Society's 14 sections serve as a voice for members of a similar discipline and help advance the specialty through unique projects, advocacy and educational programming. The chapters create opportunities for members to become known by their peers, participate in their community, interact with local and national leaders, and discuss the impact of national issues affecting their communities. Members of each chapter and section communicate through the Society's eRooms. For recent updates on the activities of each section and chapter, visit the eCommunity at www.sccm.org.

Anesthesiology Section

Section Elections to be Held at Congress

Gerald Maccioli, MD, FCCM has unfortunately stepped down as the section's Chair-Elect due to his commitments to the American College of Critical Care Medicine (ACCM). The Section's Secretary-Treasurer, Louis Brusco, MD, FCCM has agreed to take over the responsibilities of Chair-Elect. Until section elections at SCCM's Annual Congress in February, Michael Ault, MD, who is serving on the section's Advisory Board, has agreed to be the interim Secretary-Treasurer. If you are interested in being considered as a candidate for the Advisory Board at the section's 2004 election, please submit your name and a letter noting your interest and your previous involvement with SCCM.

Clinical Pharmacy and Pharmacology Section

CPP Section's Projects Near Completion

A national survey (n=7500 hospitals) of critical care pharmacy services is nearing completion and results are expected to be available in 2004.

The list of journal and textbook publications authored by CPP section members has recently been updated and is posted on www.sccm.org.

Watch for the preliminary results from the multicenter aspiration pneumonia project, which have been submitted for possible presentation at SCCM's Congress in February.

Submit your 2004 strategic planning award proposals and program ideas for the 2005 Congress.

Lastly, section members are actively involved in planning for a 2004 SCCM Critical Care Pharmacology course.

Vital News, *Critical Connections'* industry news page, highlights new developments in the critical care community. The Society of Critical Care Medicine does not endorse and/or promote any of the companies, products or programs mentioned in Vital News.



Organizations Support JCAHO's Universal Protocol

More than 40 leading medical and healthcare groups have now endorsed the Joint Commission on Accreditation of Healthcare Organizations' (JCAHO) Universal ProtocolTM to standardize pre-surgery procedures by verifying the correct patient, the correct procedure and the correct surgical site. The Protocol is a nationwide initiative aimed at preventing surgical errors and will become effective on July 1, 2004 for all Joint Commission-accredited hospitals, ambulatory care surgery centers and office-based surgery sites. For more information, visit www.jcaho.org.

Medical Records in Britain Go Electronic

The National Health Service (NHS), which sets overall health policy in England, recently announced that every NHS patient in England will have an individual electronic NHS Care Record by 2010. The NHS Care Records Service will provide all 50 million NHS patients with an individual electronic patient record, which will detail key treatments and care within either the health service or social care. For the first time, information about patients will be mobile.

"The NHS Care Record will completely revolutionize the way that information is accessed and will make available efficient, secure and integrated records to the right people at the right time," comments Britain's Health Secretary John Reid.

The care records are expected to cut down on time wasted by healthcare workers searching for missing records and will eliminate the need for bulky paper files. By late 2004, the records will contain basic patient information and health details. As the records grow over time, the public will be able to access their NHS Care Record themselves, allowing them to become more involved in making decisions about their treatment.

A number of additional countries, including the United States, are also working toward electronic patient records. (See page 10 in this issue for more information on U.S. efforts to implement technology in the ICU.) To learn about NHS's efforts in the United Kingdom, visit www.nhs.uk.

Respiratory Care Section

Receive a Complimentary Subscription to ADVANCE for Managers of Respiratory Care

Members of the Society of Critical Care Medicine's Respiratory Care Section currently receive a complimentary subscription to *ADVANCE for Managers of Respiratory Care*. Please enroll/renew by completing the subscription card attached to the publication, call (800) 355-1088, Monday through Friday, 8:00 a.m. - 6:00 p.m., or visit www.advanceweb.com to continue receiving this publication without interruption. The offer is available to individuals residing in the United States and U.S. territories only.

Surgery Section

Attend the Section's Annual Business Meeting

The Surgery Section will discuss several items of interest at the Annual Business Meeting. Vital information on the future of Surgical Critical Care will be covered, as well as an update on educational aspects. All members are strongly encouraged to attend the business meeting.

If you have not already done so, please be sure to vote for the candidates of your choice for Council seats. You should choose those members who will best represent the needs of the Surgery Section as well as the Society as a whole.

The Annual Symposium will be hosted in Orlando at one of the premier conference hotels. Section members will be participating in both plenary sessions and the scientific forum.

news

Vital

Carolina/Virginia Chapter

Chapter Completes Annual Symposium Program

The Chapter's Annual Scientific Symposium program is complete! Program highlights include:

Regulatory Forces and the Changing Environment in the ICU

New Techniques in Weaning from Mechanical Ventilation

Blood Conservation

VTE Prophylaxis and Management

Hypertensive Crisis

Antifungal Therapy

Alternative Medicines in the ICU

The symposium will be held June 18-19, 2004 in Williamsburg, Virginia. A pre-symposium FCCS course will be held on June 16-17, 2004.

Please be sure to attend our Chapter Business Meeting at the 33rd Critical Care Congress in Orlando on Monday, February 23 from 8:00 a.m. – 9:30 am.

For chapter information, please contact Gretchen M. Brophy, PharmD at gbrophy@vcu.edu.

New Jersey and Pennsylvania Chapters

The Society of Critical Care Medicine and the New Jersey and Pennsylvania Chapters will be holding their Second Annual Joint meeting on March 6-7, 2004 at the Philadelphia Marriott in Center City Philadelphia, Pennsylvania. The world famous Philadelphia Flower Show will be held at the Convention Center connected to the hotel this same weekend. For more information contact Linda Bartolo at (973) 597-0938.

States Benefit Modestly from Federal Bioterrorism Funds

A recent study conducted by the Trust for America's Health (TFAH), a nonprofit organization based in Washington, D.C., found that after two years and nearly \$2 billion of federal bioterrorism preparedness funding, states are only modestly better prepared to respond to health emergencies than they were prior to September 11, 2001.

The TFAH report, "Ready or Not? Protecting the Public's Health in the Age of Bioterrorism," examines 10 key indicators to assess areas of improvement and of ongoing vulnerability in the United States' effort to prepare against bioterrorism and other large-scale health emergencies. The report found that progress has been made in most states to expand the health emergency communications network, upgrade public health laboratories and develop initial bioterrorism response plans. However, serious concerns still exist, such as shortages of trained professionals, imbalanced resource allocation, and inadequate vaccination/antidote supplies.

"Now is the time to get serious about developing an all-hazards approach to public health to ensure we are ready for the range of possible threats we face," says Shelley A. Hearne, DrPH, executive director of TFAH. The TFAH recommends a number of measures to ensure sufficient preparedness. To view the report in its entirety, visit www.healthyamericans.org.



Career Central is a feature of the Society's Web site that allows people to post and search job openings within moments. Job seekers can access Career Central to search up-to-date job openings using category, location, or keywords and can send a message to the prospective employer directly from the search results page.

To use this exciting job tool, simply go to the SCCM Web site at www.sccm.org, click on the *Career Central* icon on the top navigation bar, and follow the links to the job search or job posting page. Contact SCCM via email (info@sccm.org) or phone (847) 827-7478 to edit, update, remove, and/or renew your ad.

Critical Care

Full-time Physician – Phoenix, Arizona

MedPro, one of the largest private multispecialty practices in Arizona, with more than 300 providers, seeks critical care physicians to build a multi-hospital critical care program. MedPro currently provides a closed unit teaching medical ICU service at Maricopa Medical Center.

MedPro has developed a mixed medicalsurgical unit at a general community hospital and plans to open additional medical-surgical coverage at other community hospitals in the metropolitan Phoenix area. These units will be open units with a designated Medical Director. At least one unit will have some house staff involvement. We seek to recruit a group of physicians who will be involved in these units, provide medical leadership, and ensure an on-call schedule that will involve coverage of the units during nights/weekends. For those who wish to paricipate in the teaching activity at Maricopa, opportunity will be provided to rotate to Maricopa every few weeks for interactions with medical residents. We are hopeful that pulmonary/critical care fellows will be present in the Maricopa unit within the near future. The division currently includes four full-time physicians with another to begin Spring 2004.

MedPro offers an outstanding work environment, competitive salary, comprehensive benefits package, malpractice coverage, and relocation assistance. Contact:

Richard W. Carlson, MD, PhD, FCCM c/o Provider Recruiting 3255 E. Elwood St. Phoenix, AZ 85034 Phone: (877) 4-MEDPRO Fax: (602) 470-5067 Email: practice@medprodoctors.com

Full-time Intensivist – Cooperstown, New York

The Division of Critical Care at the Mary Imogene Bassett Hospital is expanding its services and is seeking an additional intensivist to provide patient care, along with house staff and medical student training, in the hospital's 14-bed Medical/Surgical/ Cardiac ICU. Bassett Healthcare, a teaching affiliate of Columbia University, is a multispecialty group practice that provides primary and tertiary care services to an eight-county region of upstate New York. The Cooperstown area offers a fine venue for outdoor activities including biking, running, canoeing, swimming, and hiking, superb indoor recreational facilities, excellent schools, and internationally-renowned museums and fine arts. We offer a competitive salary, faculty appointment and liberal fringe benefits. BE/BC intensivists with a proven ability to lead a multidisciplinary team of clinicians, and dedicated to teaching should apply. Contact:

Debra Ferrari Bassett Healthcare One Atwell Road Cooperstown, NY 13326 Phone: (607) 547-6982 Fax: (607) 547-3844 Email: debra.ferrari@bassett.org Web site: www.bassett.org

Full-time Physician – Dayton, Ohio

Nineteen physician multi-specialty group seeking fifth intensivist for private practice. Located in Southwestern, Ohio, near Cincinnati, this metropolitan area of 600,000 offers many cultural, sports and recreational activities. Excellent school system and affordable housing. Competitive salary and benefits package. Not a J-1 Visa opportunity. Contact:

Becky Kronauge 33 West Rahn Road #102 Dayton, OH 45429 Phone: (937) 433-8990 Fax: (937) 433-8691 Email: rkronauge@sdacc.com Web site: www.sdacc.com

(continued on page 22)

From Critical to Controlled...



Onset of action: 2 minutes

Half life: 9 minutes
Duration of action: 10 to 20 minutes

Beta1 selectivity at lower doses*

* Beta, selectivity is not absolute: at higher doses esmolol HCI begins to inhibit beta, receptors.

Contraindicated in patients with sinus bradycardia, heart block greater than first degree, cardiogenic shock, and overt cardiac failure.

Should not be used for treatment of hypertension due primarily to vasoconstriction associated with hypothermia or to prevent tachycardia and/or hypertension.

The most common side effect was hypotension; asymptomatic (25%) and symptomatic (12%), mainly dizziness and diaphoresis. Hypotension usually reverses within 30 minutes of decrease of dose or termination of infusion.

Relative Contraindications—Use with caution and monitor carefully during infusion for patients with LV dysfunction, CHF, hypotension, reactive airway disease, and diabetes. In general, patients with bronchospastic disease should not receive beta blockers. Due to the relative beta₁ selectivity and titratability, esmolol HCI may be used with caution in patients with bronchospastic disease. Titrate to the lowest possible dose.



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Full-time Intensivist – Green Bay, Wisconsin

Second adult intensivist sought to join expanding critical care medicine program at 547-bed licensed Level II Trauma Center, 28 ICU beds, with an active dialysis and neurosurgical programs. The position enjoys the support of the medical staff and the hospital. We offer a competitive salary and benefits package with relocation assistance. Enjoy a four seasons climate with outstanding cultural and outdoor recreational opportunities. Easy access to Milwaukee and Chicago. Contact:

David Nyman P.O. Box 13508 Green Bay, WI 54307-3508 Phone: (800) 236-3030 Ext. 8076 Fax: (920) 431-3043 Email: dnyman@stvgb.org Web site: www.stvgb.org

Pediatric Critical Care

Full-time Attending, Pediatric Critical Care – Washington, D.C.

Children's National Medical Center's (CNMC) division of critical care medicine has an opening for a tenth pediatric intensivist. We are considering candidates at the associate professor or assistant professor level. Assistant professor candidates should have the ability to achieve excellence in their chosen areas of concentration, and associate professor candidates should be able to demonstrate such ability. The PICU at CNMC is a 22-bed multidisciplinary unit. In addition to this unit, the intensivist group provides part-time clinical coverage for one smaller PICU and consults at a third ICU. A new PICU of at least 30 beds is expected to be completed within three years. EOE,M/F/D/V. Contact:

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(Esmolol Hydrochloride) 250 mL Ready-to-use Bags Iso-Osmotic Solution of Esmolol Hydrochloride in Sodium Chloride FOR INTRAVENOUS USE. CAN BE USED FOR DIRECT INTRAVENOUS USE. Esmolol Hydrochloride concentration = 10 milligrams/mL (10,000 micrograms/mL) Single Patient Use Only. No Preservative Added.

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BREVIBLOC INJECTION

(Esmolol Hydrochloride) 10 mL Ready-to-use Vials Iso-Osmotic Solution of Esmolol Hydrochloride in Sodium Chloride FOR INTRAVENOUS USE. CAN BE USED FOR DIRECT INTRAVENOUS USE. Esmolol Hydrochloride concentration = 10 milligrams/mL (10,000 micrograms/mL) Single Patient Use Only. No Preservative Added.

BREVIBLOC CONCENTRATE

(Esmolol Hydrochloride) 10 mL Ampuls for Dilution NOT FOR DIRECT INTRAVENOUS INJECTION.

Esmolol Hydrochloride concentration = 250 milligrams/mL (250.000 micrograms/mL) AMPULS MUST BE DILUTED PRIOR TO ITS INFUSION - SEE DOSAGE AND

ADMINISTRATION, Directions for Use of the Brevibloc Concentrate 10 mL Ampul (250 milligrams/mL) in full prescribing information. BRIEF SUMMARY. FOR FULL PRESCRIBING INFORMATION SEE PRODUCT INSERT.

INDICATIONS AND USAGE

INDICATIONS AND USAGE Supraventricular Tachycardia BREVIBLOC (Esmolol Hydrochloride) is indicated for the rapid control of ventricular rate in patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other emergent circumstances where short term control of ventricular rate with a short-acting agent is desirable. BREVIBLOC is also indicated in noncompensatory sinus tachycardia where, in the physician's judgment, the rapid heart rate requires specific intervention. BREVIBLOC is not intended for use in chronic settings where transfer to another agent is anticipated.

transfer to another agent is anticipated. Intraoperative and Postoperative Tachycardia and/or Hypertension BREVIBLOC (Esmolol Hydrochloride) is indicated for the treatment of tachycardia and hypertension that occur during induction and tracheal intubation, during surgery, on emergence from anesthesia, and in the postoperative period, when in the physician's judgment such specific intervention is considered indicated. Use of BREVIBLOC to prevent such events is not recommended.

CONTRAINDICATIONS BREVIBLOC (Esmolol Hydrochloride) is contraindicated in patients with sinus bradycardia, heart block greater than first degree, cardiogenic shock or overt heart failure (see **WARNINGS**).

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Iow. Decrease of dose or termination of infusion reverses hypotension, usually within 30 minutes. Cardiac Failure: Sympathetic stimulation is necessary in supporting circulatory function in congestive heart failure, and beta blockade carries the potential hazard of further depressing myocardial contractility and precipitating more severe failure. Continued depression of the myocardium with beta blocking agents over a period of time can, in some cases, lead to cardiac failure. At the first sign or symptom of impending cardiac failure, BREVIBLOC (Esmolol Hydrochloride) should be withdrawn. Although withdrawal may be sufficient because of the short elimination half-life of BREVIBLOC, specific treatment may also be considered (see **OVERDOSAGE** in full prescribing information). The use of BREVIBLOC for control of ventricular response in patients with supraventricular arrhythmias should be undertaken with caution when the patient is compromised hemodynamically or is taking other drugs that decrease any or all of the following: peripheral resistance, myocardial filling, myocardial contractility, or electrical impulse propagation in the myocardium. Despite the rapid onset and offset of the effects of BREVIBLOC, several cases of death have been reported in complex clinical states where BREVIBLOC was presumably being used to control ventricular rate.

Intraoperative and Postoperative Tachycardia and/or Hypertension: BREVIBLOC (Esmolol Hydrochloride) should not be used as the treatment for hypertension in patients in whom the increased blood pressure is primarily due to the vasoconstriction associated with hypothermia.

Biodo pressure is primarily due to the vasoconstriction associated with hypothermia. **Bronchospastic Diseases:** PATIENTS WITH BRONCHOSPASTIC DISEASES SHOULD, IN GENERAL, NOT RECEIVE BETA BLOCKERS. Because of its relative beta₁ selectivity and titratability, BREVIBLOC (Esmolol Hydrochloride) may be used with caution in patients with bronchospastic diseases. However, since beta₁ selectivity is not absolute, BREVIBLOC should be carefully titrated to obtain the lowest possible effective dose. In the event of bronchospasm, the infusion should be terminated immediately; a beta₂ stimulating agent may be administered if conditions warrant but should be used with particular caution as patients already have rapid ventricular rates.

Diabetes Mellitus and Hypoglycemia: BREVIBLOC (Esmolol Hydrochloride) should be used with caution in diabetic patients requiring a beta blocking agent. Beta blockers may mask tachycardia occurring with hypoglycemia, but other manifestations such as dizziness and sweating may not be significantly affected

PRECAUTIONS General Infusion concent thrombophlebitis Infusion concentrations of 20 mg/mL were associated with more serious venous irritation, including thrombophlebitis, than concentrations of 10 mg/mL. Extravasation of 20 mg/mL may lead to a serious local reaction and possible skin necrosis. Concentrations greater than 10 mg/mL or infusion into small veins or through a butterfly catheter should be avoided.

Because the acid metabolite of BREVIBLOC is primarily excreted unchanged by the kidney, BREVIBLOC (Esmolol Hydrochloride) should be administered with caution to patients with impaired renal function. The elimination half-life of the acid metabolite was prolonged ten-fold and the plasma level was considerably elevated in patients with end-stage renal disease.

Care should be taken in the intravenous administration of BREVIBLOC as sloughing of the skin and necrosis have been reported in association with infiltration and extravasation of intravenous infusions. Drug Interactions

Catecholamine-depleting drugs, e.g., reserpine, may have an additive effect when given with beta blocking agents. Patients treated concurrently with BREVIBLOC (Esmolol Hydrochloride) and a catecholamine depletor should therefore be closely observed for evidence of hydrochloriden or marked bradycardia, which may result in vertigo, syncope, or postural hypotension. A study of interaction between BREVIBLOC and warfarin showed that concomitant administration of

BREVIBLOC and warfarin does not alter warfarin plasma levels. BREVIBLOC concentrations were equivocally higher when given with warfarin, but this is not likely to be clinically important. When digoxin and BREVIBLOC were concomitantly administered intravenously to normal volunteers, there was a 10-20% increase in digoxin blood levels at some time points. Digoxin did not affect BREVIBLOC pharmacokinetics. When intravenous morphine and BREVIBLOC were concomitantly administered in normal subjects, no effect on morphine blood levels was seen, but BREVIBLOC steady-state blood levels were increased by 46% in the presence of morphine. No other pharmacokinetic parameters were observed. parameters were changed.

The effect of BREVIBLOC on the duration of succinylcholine-induced neuromuscular blockade was studied in patients undergoing surgery. The onset of neuromuscular blockade by succinylcholine was unaffected by BREVIBLOC, but the duration of neuromuscular blockade was prolonged from 5 minutes to 8 minutes. Although the interactions observed in these studies do not appear to be of major clinical importance, BREVIBLOC should be titrated with caution in patients being treated concurrently with digoxin, morphine, succinylcholine or warfarin.

While taking beta blockers, patients with a history of severe anaphylactic reaction to a variety of allergens may be more reactive to repeated challenge, either accidental, diagnostic, or therapeutic. Such patients may be unresponsive to the usual doses of epinephrine used to treat allergic reaction. Caution should be exercised when considering the use of BREVIBLOC and verapamil in patients with

depressed myocardial function. Fatal cardiac arrests have occurred in patients receiving both drugs. Additionally, BREVIBLOC should not be used to control supraventricular tachycardia in the presence of agents which are vasoconstrictive and inotropic such as dopamine, epinephrine, and norepinephrine because of the danger of blocking cardiac contractility when systemic vascular resistance is high. Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenesis, mutagenesis, impairment or retruing Because of its short term usage no carcinogenicity, mutagenicity or reproductive performance studies have been conducted with BREVIBLOC (Esmolol Hydrochloride).

Studies have been conducted with BREVIBLOC (Estimotor Hydrochionde). **Pregnancy Category C** Teratogenicity studies in rats at intravenous dosages of BREVIBLOC (Esmolol Hydrochloride) up to 3000 mcg/kg/min (3 mg/kg/min) (ten times the maximum human maintenance dosage) for 30 minutes daily produced no evidence of maternal toxicity, embryotoxicity or teratogenicity, while a dosage of 10,000 mcg/kg/min (10 mg/kg/min) produced maternal toxicity and lethality. In rabbits, intravenous dosages up to 1000 mcg/kg/min (1 mg/kg/min) for 30 minutes daily produced no evidence of maternal toxicity, embryotoxicity or teratogenicity, while 2500 mcg/kg/min (2.5 mg/kg/min) produced minutes minutes and intravenues and intravenues and intravenues and toxicity and interesed fetal resorptions.

Although there are no adequate and well-controlled studies in pregnant women, use of esmolol in the last trimester of pregnancy or during labor or delivery has been reported to cause fetal bradycardia, which continued after termination of drug infusion. BREVIBLOC should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers It is not known whether BREVIBLOC (Esmolol Hydrochloride) is excreted in human milk; however, caution should be exercised when BREVIBLOC is administered to a nursing woman.

Pediatric Use The safety and effectiveness of BREVIBLOC (Esmolol Hydrochloride) in pediatric patients have not been established.

ADVERSE REACTIONS

ADVERSE REACTIONS The following adverse reaction rates are based on use of BREVIBLOC (Esmolol Hydrochloride) in clinical trials involving 369 patients with supraventricular tachycardia and over 600 intraoperative and postoperative patients enrolled in clinical trials. Most adverse effects observed in controlled clinical trial settings have been mild and transient. The most important adverse effect has been hypotension (see WARNINGS). Deaths have been reported in post-marketing experience occurring during complex clinical states where BREVIBLOC was presumably being used simply to control ventricular rate (see WARNINGS, Cardiac Failure). Cardianceaulty. Sumtomatic hypotension (dimension dimension (dimension) occurred in 12% of extincts and

ventricular rate (see WARNINGS, Cardiac Pallure). Cardiovascular–Symptomatic hypotension (diaphoresis, dizziness) occurred in 12% of patients, and therapy was discontinued in about 11%, about half of whom were symptomatic. Asymptomatic hypotension occurred in about 25% of patients. Hypotension resolved during BREVIBLOC (Esmolol Hydrochloride) infusion in 63% of these patients and within 30 minutes after discontinuation of infusion in 80% of the remaining patients. Diaphoresis accompanied hypotension in 10% of patients. Peripheral ischemia occurred in approximately 1% of patients. Pallor, flushing, bradycardia (heart rate less than 50 beats per minute), chest pain, syncope, pulmonary edema and heart block have each been reported in less than 1% of patients. In two patients without supraventricular tachycardia but with serious coronary artery disease (post inferior myocardial infarction or unstable angina), severe bradycardia/sinus pause/saystole has developed, reversible in both cases with discontinuation of treatment. Central Meruna System—Dizziness has occurred in 3% of natients: somolence in 3% confusion

Central Nervous System—Dizziness has occurred in 3% of patients; somnolence in 3%; confusion, headache, and agitation in about 2%; and fatigue in about 1% of patients. Paresthesia, asthenia, depression, abnormal thinking, anxiety, anorexia, and lightheadedness were reported in less than 1% of patients. Seizures were also reported in less than 1% of patients, with one death.

 ${\it Respiratory-} {\it Bronchospasm},$ wheezing, dyspnea, nasal congestion, rhonchi, and rales have each been reported in less than 1% of patients.

Gastrointestinal-Nausea was reported in 7% of patients. Vomiting has occurred in about 1% of patients. Dyspepsia, constipation, dry mouth, and abdominal discomfort have each occurred in less than 1% of patients. Taste perversion has also been reported.

Skin (Infusion Site)-Infusion site reactions including inflammation and induration were reported in about 8% of patients. Edema, erythema, skin discoloration, burning at the infusion site, thrombophlebitis, and local skin necrosis from extravasation have each occurred in less than 1% of patients. Miscellaneous-Each of the following has been reported in less than 1% of patients: Urinary retention, speech disorder, abnormal vision, midscapular pain, rigors, and fever.

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- NDC 10019-015-01, 100 mg 10 mL Ready-to-use Vials, Package of 25
- BREVIBLOC CONCENTRATE NDC 10019-025-18, 2500 mg - 10 mL Ampuls for Dilution, Package of 10

Store at 25°C (77°F). Excursions permitted to 15°-30°C (59°-86°F). [See USP Controlled Room Temperature.] PROTECT FROM FREEZING. Avoid excessive heat. Baxter

Baxter Healthcare Corporation Deerfield IL 60015 USA

BREVIBLOC INJECTION and BREVIBLOC CONCENTRATE manufactured by Faulding Puerto Rico, Inc. P.O. Box 471 Aguadilla, PR 00604 USA

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For Product Inquiry 1 800 ANA DRUG (1-800-262-3784)

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Welcome new members

Members are the driving force behind the growth of the Society of Critical Care Medicine and the continued pursuit of excellence in the field of critical care. The Society is pleased to welcome the following new members to the world's largest multiprofessional, multidisciplinary organization dedicated to the advancement of critical care. (As of November 2003)

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