

ICU

MANAGEMENT

THE OFFICIAL MANAGEMENT AND PRACTICE JOURNAL

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NUTRITION

Utilising nutrients as a therapeutic strategy?
Nutritional challenges in obese, obstetric patients
Strict protocols for successful enteral feeding



PLUS:

- **The Aftermath Of AH1N1:**
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Improving Safety And Quality
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NUTRITION



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ICU Management

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One needn't have a medical license or years of training as a clinician to understand the simple importance of nutrition. There are numerous clichés that embody this very sentiment (“An apple a day keeps the doctor away...”; “Chicken soup will heal what ails you...”) What is commonly accepted is that proper nutrition can not only guard against ailments, but aid in the rebuilding of muscle, and help to restore energy and strength in recovery from illness.

Of course, in practice, in the ICU, treating critically ill patients, this premise becomes much more complex. How should nutrition be given? What type? How much? How should we base our guidelines? Over the years, much consideration has been given to this broad topic of nutrition in intensive care, and the accepted guidelines have changed with the tides.

In this issue, Dr. Martindale tackles the validity of the pharmaconutrition evolution and Dr. Sanchez Nava underlines the importance of utilising strict protocols for success with enteral nutrition in ICU pa-

tients. As many nutrition questions arise with regards to specific groups of critically ill patients, we have included an article from Dr. Hiesmayr on managing the nutritional challenges of obese patients as well as an

benefits of utilising drug eluting stents by Dr. Rodriguez of Argentina.

Germany takes centre stage in this edition of the journal with an extensive overview of its healthcare system; a

“A slender and restricted diet is always dangerous in chronic and in acute diseases”

Hippocrates 400 B.C.

interesting focus on nutritional support of obstetric patients contributed by a team of nutritionists.

It is difficult to believe that it has been more than a year since the outbreak of the AH1N1 virus in Mexico and subsequent global pandemic. Dr. Vasquez de Anda marks the occasion with some reflection on what organisational changes have been made since the crisis, and those that are necessitated in anticipation of a future virus with epidemic potential. Also in our Matrix, we feature an engrossing discussion of balancing the risk and

focus on the specialised nature of neurointensive care units and; in our Management section, the introduction of a unique concept in the structural organisation of intensive care; aptly named “ICU Outside the Box”, which is currently being utilised within a German hospital.

Teamwork is oft-touted as a catchword of our times. Within our units, the idea holds a great deal of merit as it is often a multidisciplinary group of care providers who must merge diagnoses, treatment ideas and daily decisions for our patients. In our Viewpoints section, Dr. Pelosi highlights the importance of this approach within any management strategy and further, as ESA President, he enlightens us on the upcoming mandates of the society in the interest of improving patient safety.

The importance of nutrition within critical care is accepted, as are some basic guidelines. As the field expands to incorporate more by way of study into additives and pharmaconutrition and is further driven by clinicians' call to improve patient outcomes and lower length of stay; more clarity and precise protocols will assuredly become mainstream.



Jean-Louis Vincent

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NEWS FROM ISICEM

CPR GUIDELINES: WHAT WILL CHANGE IN 2010?

The International Liaison Committee on Resuscitation (ILCOR) is presently in the process of revising its guidelines on CPR, the last set of which were published in 2005. This important topic was covered at an interactive Round Table session during the 30th International Symposium on Intensive Care and Emergency medicine. Five experts in the field of resuscitative medicine who are actively involved in this process spoke about the areas of controversy within this field and,



Picture 1. 30th ISICEM

without giving the game away (!), spoke about some of the possible changes. The panel started with the controversy related to hands-only CPR. The panel felt that hands-only CPR may be easier to apply, particularly for the layperson, but were concerned that the importance of ventilation should not be forgotten and that while hands-only CPR may be adequate initially in a young patient with

a cardiac etiology rapid response arrest, in other patients with hypoxic etiology or longer response times, it may not be appropriate. Teaching laypersons to distinguish between such patients would be difficult, and there were also concerns that if the hands-only approach was taught, rescue breathing techniques would rapidly be forgotten and unable to be used if needed. The panel then moved on to issues of intubation and while some felt indeed that endotracheal intuba-

tion could be delayed and other techniques used for airway management, others stressed again the importance of considering the individual patient and the skills and training of the attending personnel. All the panel members stressed the need to limit as much as possible any interruption in chest compressions. The need for defibrillation was also discussed with an emphasis on careful tim-

ing and a more individualised approach.

The question of when and how to use hypothermia was raised by the audience with the panel suggesting that this would be one area where some flexibility could be incorporated into the new guidelines, but that all post-arrest centres should have facilities to offer hypothermia. Finally, the confusion between different algorithms for the paediatric and adult populations was raised with a suggestion that for simplicity and where possible these would be brought into alignment. In conclusion, the panel stressed that the guidelines had not yet been finalised and data were still being reviewed and discussed but that for many aspects the levels of evidence was still limited so that only low-grade recommendations would be offered. In principle, the aim is to keep things as simple as possible and limit changes as much as possible.

Members of the Round Table:

Moderator: Peter Brindley
(Edmonton, Canada)

Topic: Anticipating the major changes in the 2010 CPR guidelines

- Jerry Nolan *(Bath, UK)*
- Robert E O'Connor *(Charlottesville, USA)*
- Kjetil Sunde *(Oslo, Norway)*
- Thomas Pellis *(Pordenone, Italy)*, and
- Paul E Pepe *(Dallas, USA)*

INDUSTRY NEWS

New In Vivo Study Finds Covidien's Mallinckrodt™ TaperGuard™ Endotracheal Tube Provides Significantly More Protection Against Microaspiration Than Conventional Tube

Covidien announced that a new in vivo study concluded that the Mallinckrodt™ TaperGuard™ endotracheal tube provided significant protection from microaspiration and lung damage compared to the Mallinckrodt™ Hi-Lo endotracheal tube. The findings were presented at the annual International Symposium on Intensive Care and Emergency Medicine (ISICEM), in Brussels.

The study - Do Endotracheal Tubes Prevent Microaspiration? - by Lichtenthal et al.

compared the Hi-Lo tube, with a barrel-shaped cuff, and the new TaperGuard tube, which features a taper-shaped cuff. In the study, subjects were intubated prior to surgery with either the Hi-Lo or TaperGuard tubes. Blue dye was injected above the tubes, and afterward, the subjects' trachea and lungs were evaluated for dye leak, bronchitis, ulceration and haemorrhagic pneumonia. The researchers found that the TaperGuard tube significantly outperformed the Hi-Lo tube in reducing dye leak and bronchitis, and also offered im-

proved, potentially clinically significant, protection in the remaining categories.

By providing a more effective fluid seal, the TaperGuard tube reduces the risk of microaspiration, which is a common problem in intubation that may lead to pulmonary complications, including ventilator-associated pneumonia (VAP) and post-operative pneumonia.

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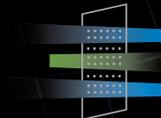


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USING SPECIFIC NUTRIENTS TO IMPROVE OUTCOME AND SHORTEN LENGTH OF STAY IN THE ICU: FACT OR FANTASY?



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Nutritional delivery in the critically ill population has radically evolved in the past 15 years from the concept of nutrition delivery to prevent malnutrition to the concept of nutrition therapy as a crucial element in maintaining vital organ function and modulating key processes such as immunity, inflammation, and anti-oxidant defenses. Utilising specific nutrients such as fish oils, arginine, glutamine, leucine, anti-oxidants, and nucleic acids as pharmaconutrients given at levels above that needed for “normal” metabolism has now become accepted as part of current ICU care throughout the world. The recent guidelines produced as a collaboration between the Society of Critical Care Medicine and the American Society of Critical Care Medicine describes the rationale and gives use of metabolic and immune modulating formulations a grade ‘A.’ This grade is supported by 15 level two studies and six level one studies (Martindale et al. 2009). Similar grade ‘A’ recommendations are made by the European Society of Enteral and Parenteral Nutrition (Weimann et al. 2006).

John Hunter in 1784 described in his book, “A treatise on blood, inflammation and gunshot wounds a mechanism of inflammation and a comment that “many types of injury produce a similar inflammation.” Sir William Osler in 1904 has been quoted as saying “except on few occasions the patient appears to die from the body’s response to infection rather than from it.” These two extremely insightful comments both made over one hundred years ago describe one of the major themes in the concept of nutritional modulation of metabolism and immunity in the critically ill in 2010. Attempting to attenuate or control the metabolic response to stress and trauma at a manageable level rather than allowing the extremes of the systemic inflammatory response (SIRS) and the lows associated with compensatory anti-inflammatory response (CARS) is now the key focus in early aggressive nutritional therapy. The metabolic response to stress is well described and includes a hyperdynamic cardiac and pulmonary response, insulin resistance, hyperglycemia, accelerated protein catabolism from the muscle, poor adaptation to starvation, increased oxidative stress, and if the response goes on unabated, complex immunological changes resulting in immune suppression (Atiyeh et al. 2008). During this hyperdynamic phase of ill-

ness, surgery or trauma the loss of lean body mass continues despite delivery of adequate enteral or parenteral protein and calories. In effect, delivery of just “calories and protein” to the hyperdynamic patient is not reversing the adverse effects of ongoing loss of lean body tissue. The ideal concept of using specific nutrients to alter this hyperdynamic response was proposed in the late 1980’s and has now become the standard of care for critically ill patient, traumatised and surgical patients.

The use of the fish oils (EPA and DHA) is at the centre of this pharmaconutrition evolution. Appropriate use of omega-3-FA can partially attenuate the metabolic response, reverse or stop the loss of lean body tissue, prevent oxidative injury and favourably modulate the inflammatory response (Calder 2010). Traditionally lipids were felt to be important in clinical nutrition but only as a caloric source, providing essential fatty acids and support the absorption of fat-soluble vitamins via micelle formation in the proximal small bowel. Currently specific lipids are being used to alter the metabolic response to stress by changes in cell membrane phospholipids, alterations in gene expression, modulating endothelial expression of ICAM-1, E-Selectin and other endothelial receptors regulating vascular

integrity and function. Additionally, EPA and DHA derivatives, including resolvins, docosatrienes, and neuroprotectins, are potent active effectors of resolution of inflammation (Mayer and Seeger 2008; Serhan 2009). Resolvins regulate polymorphonuclear neutrophil (PMN) transmigration. Docosanoids and neuroprotectins are both derived from DHA and have potent neuroprotective properties. Neuroprotectin decreases neutrophil infiltration, proinflammatory gene signaling, and NFκB binding. Neuroprotectin D1 (NPD1) has been found to reduce neural infarct volume by half in an animal ischaemia-reperfusion model (Bazan 2005). These protective mediators are found to be highly conserved among species, from fish to mammals (Serhan and Savill 2005). With the discovery of these compounds it is acknowledged that resolution of inflammation is an active process rather than a passive time dependent process. Fish oils also have a regulatory influence on the vagus nerve. The vagus has a well know bidirectional and multi-level interaction between the central nervous system and the innate and adaptive immune system. Fish oils have recently been shown to dampen the inflammatory response mediated via the vagal fibers.

In the past, some controversy has arisen around the use of the amino acid arginine in the ICU setting (Suchner et al. 2002). Arginine, despite being only semi-essential under normal physiologic conditions, plays a significant role in the intermediary metabolism of the critical care patient. L-Arginine is available from endogenous synthesis (via citrulline conversion in kidney), protein breakdown, and dietary sources (diet only contributing about 20 to 25% of total arginine supply). Arginine is a prominent intermediate in polyamine synthesis (cell growth and proliferation), proline synthesis (wound healing and collagen synthesis), nitric oxide production (via

eNOS, iNOS, nNOS), and modulator of lymphocyte proliferation and differentiation. Clearly, arginine balance and availability will affect outcomes in the critically ill patient (Zhou and Martindale 2007). The de-novo synthesis and dietary intake is commonly reduced in critical illness. While supply is

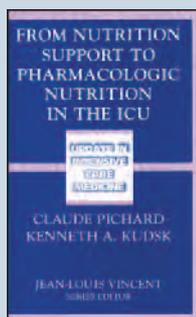
“The nutrients have been shown to lower the incidence and severity of acute lung injury and adult respiratory distress syndrome, decrease adverse cardiac events and enhance early recovery from gastrointestinal surgery and trauma.”

decreased the cellular demand for arginine is increased. This increased demand is driven mainly by the upregulation of arginase and iNOS in the trauma, surgery and critical care setting (Morris 2009).

The speculation that arginine poses a threat to the critically ill patient is mainly based on the theoretical concept that the critically ill population commonly has upregulated iNOS and that by delivering additional arginine as the substrate for up-regulated iNOS would result in excess nitric oxide production with consequent vasodilation. An alternate, equally valid

BOOKS IN REVIEW

From Nutrition Support to Pharmacologic Nutrition in the ICU



Series: Update in Intensive Care Medicine / Pichard, Claude; Kudsk, Kenneth A. [Eds.]

1st ed. 2000. 2nd printing, 2002, XIV, 483 p. 72 illus., Softcover

ISBN: 978-3-540-42604-2

Critically ill and critically injured patients require specialised nutrition support to avoid the complications of progressive malnutrition. There is a paucity of information providing practical solutions to these difficult clinical problems. From Nutrition Support to Pharmacologic Nutrition in the ICU focuses on the theoretical and practical aspects of the management of this high-risk patient population. Each

chapter presents a state-of-the-art discussion of nutritional and metabolic issues relevant to this resource-intensive patient population and contains current references, liberal tables and figures, and the personal insights of recognized international leaders in this field.

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argument is that controlled vasodilation is beneficial in critical illness and sepsis. Shock by definition is “inadequate delivery of oxygen and nutrients to maintain normal tissue and cellular function” (Jones and Puskarich 2009). It may be that the vasodilation from arginine is an adaptive mechanism to increase delivery of oxygen to the cell (Zhou and Martindale 2007). Until recently few studies had evaluated arginine as a single agent in the critically ill and septic patient. Luiking et al. recently published an elaborate metabolic study of citrulline and arginine in septic patients. They concluded that additional arginine had no adverse effects in sepsis (Luiking et al. 2009). A study by Kao et al. evaluating arginine in sepsis concluded that, in fact, arginine may be deficient in sepsis via inadequate de-novo synthesis (Kao et al. 2009). So the theory that additional arginine delivered to the medical critically ill or septic population would be detrimental is unfounded and in fact the exact opposite may be the case. It now appears from the articles and human studies listed above that arginine may in fact be deficient in critical illness and should be supplemented.

In addition to arginine the amino acid glutamine has gained support in the critical care setting. Over the past 20 years, glutamine has been reported to offer a myriad of benefits, including maintenance of acid-base balance, primary fuel for rapidly proliferating cells (i.e., enterocytes and lymphocytes), precursor in the synthesis of endogenous antioxidant glutathione, increase levels of arginine via the ornithine pathway, reduction of insulin resistance during stress and a key substrate for gluconeogenesis (Wischmeyer 2008). Recent reports that glutamine induces heat-shock protein in numerous tissue beds is yet another beneficial effect of this versatile amino acid (Wischmeyer 2008). By enhancing the chaperone proteins, the cell protects itself from subsequent stress (Hamiel et al. 2009).

Over 50 human studies have reported the effects of combinations of metabolically active nutrients, including fish oils (DHA and EPA), arginine, glutamine, nucleic acids, and anti-oxidants with the majority showing some beneficial influence in outcome and cost effectiveness. The disease states benefiting from these metabolic modulating formulations are wide ranging and spread over several organ systems. The nutrients have been shown to lower the incidence and severity of acute lung injury and adult respiratory distress syndrome, decrease adverse cardiac events and enhance early recovery from gastrointestinal surgery and trauma. Metabolic modulating formulas also have been shown to attenuate some of the adverse metabolic effects of sepsis. Not only have these human clinical studies shown benefit in shortening hospital stay and decreasing infections, but several have also reported lower mortality rates (Macario et al. 2005; Tsekos et al. 2004; Heller et al. 2006). Although the data overwhelmingly support the use of metabolically active specific nutrients, the optimal delivery route,

timing of delivery, and dosage in trauma and critical care settings will have significant influence that must be sorted out.

The concept of pharmaconutrition is now clearly accepted by most clinicians worldwide. Subsequent studies will further elaborate which ICU populations will maximally benefit. The use of fish oils, arginine, glutamine and other metabolically active nutrients is now a major part of trauma and critical care nutrition protocols as noted by the Society of Critical Care Medicine, ASPEN and ESPEN Guidelines. All three of these major societies have given an ‘A’ grade to the use of immune and metabolically active agents in specific populations (Martindale et al. 2009; Weimann et al. 2006). Whether nutrients are used in combination or individually, these agents should be part of the intensivist’s armamentarium for improving outcome and cost effective ICU care. ■

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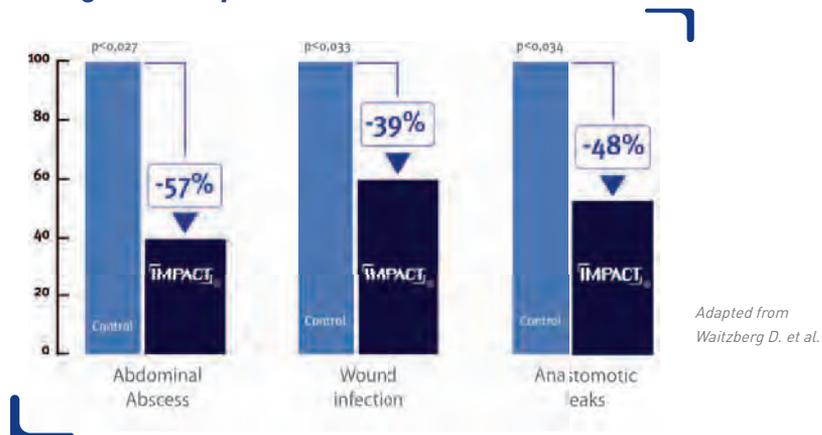
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SUCCESSFUL ENTERAL NUTRITION IN CRITICALLY ILL PATIENT WITH A STRICT PROTOCOL



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Introduction

During the last two decades, nutritional support has been recognised as a vital component in the management of critically ill patients. Nutrition supplies vital cells substrates, antioxidants, vitamins and minerals that optimise recovery from illness (Heyland 1998). Critically ill patients are in constant hypercatabolism. Even if patients had a good nutritional status before they entered the ICU, they are at risk of developing malnutrition (Monk 1996). Protein energy malnutrition is a major problem in severely ill hypercatabolic patients in the ICU (Jolliet et al. 1998). Critical illnesses, stress, and surgery place increased demands on the body's nutritional requirements. These conditions promote a catabolic state and negative nitrogen balance. Prolonged bed rest and inactivity, per se, produce a negative nitrogen balance in healthy individuals (Scheld et al. 2001).

Malnutrition is a common problem in hospitalised patients. As many as 40% of adult patients are seriously malnourished at the time of their admission, and two thirds of all patients experienced deterioration of their nutritional status during their hospital stay (Cera et al. 1997). Numerous tools and scoring methods are used to screen for malnutrition in the community and hospitals (Jones 2002). Most of these tools are either not validated clinically, or are not user-friendly enough for busy clinics. Body mass index (BMI) is a simple and objective measurement for determining the nutritional status and is an important component of several malnutrition screening tools (Kondrup et al. 2003). Patients with BMI less than 18.5 Kg/m² are classified as severely malnourished by these tools. Subjective global assessment (SGA) scores, determined by medical history on seven items and clinical findings on four items, is a well-validated tool for screening for malnutrition (Detsky et al. 1987).

Nutritional Support Routes

The optimal route of nutrition support has been studied extensively. The evidence shows that, in critically ill patients with an intact GI tract, the use of enteral nutrition compared with parenter-

al nutrition is associated with a significant reduction in infections (Gramich et al. 2004). The use of parenteral nutrition was associated with an increase in infectious complications, catheter related bloodstream infections, and noninfective complications (Peter et al. 2005). A significant reduction in hospital length of stay (LOS) was also seen with the use of enteral nutrition in these patients.

According to the Canadian Clinical Practice Guidelines for nutrition support, when considering nutritional support in critically ill patients with an intact GI tract, enteral nutrition is strongly recommended over parenteral nutrition. Enteral Nutrition has been advocated as a means of reducing mucosal atrophy and increased intestinal permeability with consequent reduction in the incidence of gut translocation and septic complications. More qualities can be attributed to enteral nutrition: It is cheaper, more physiological and safer overall in this patient group (Heyland et al. 2003).

Enteral nutrition has been demonstrated to:

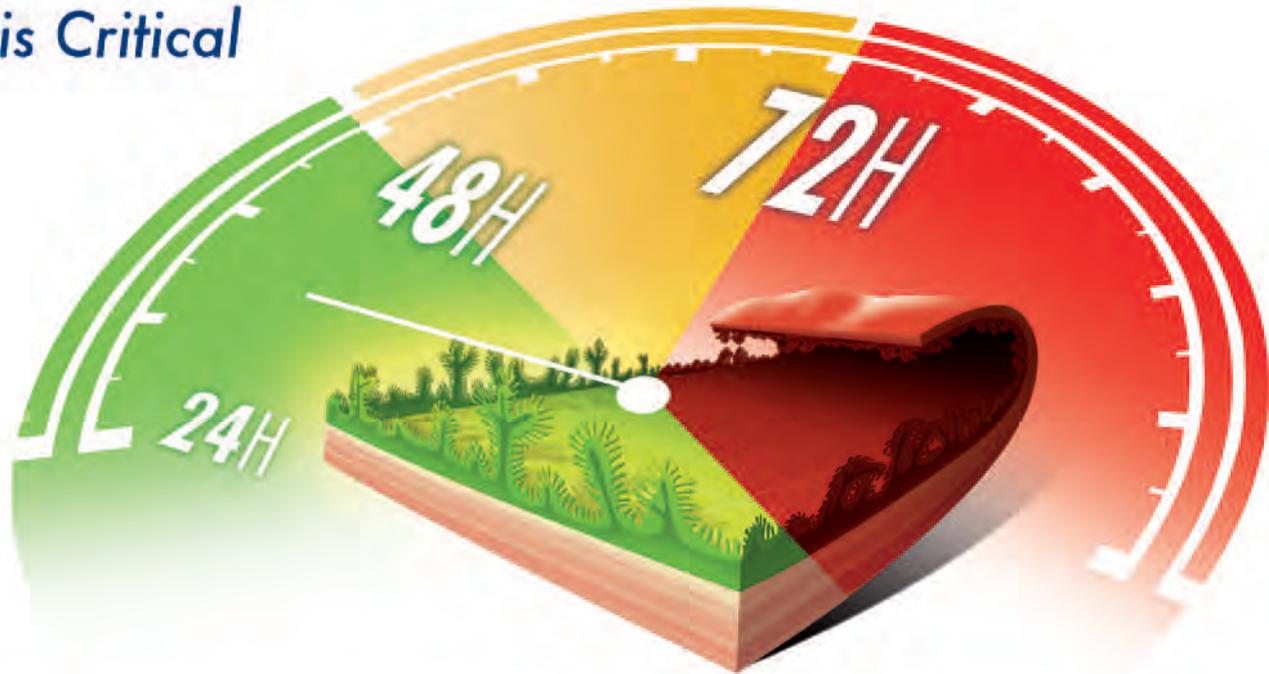
- Improve nitrogen balance;
- Increase wound healing,;
- Improve host immune function;
- Increase cellular antioxidant system;
- Decrease hypermetabolic response to tissue injury;
- Preserve intestinal mucosal integrity immunity;
- Prevent increased bacterial translocation, (Minard and Hudsk 1994) and additionally; and
- Early feeding decrease infections complications and length of stay (Marik and Zaloga 2001).

The Canadian Nutrition Support Clinical Practice Guidelines recommend early enteral nutrition (within 24-48 hrs following admission) in critically ill patients (Heyland et al. 2003).

In the ICU at Hospital San José we start nutrition as soon as possible. On average, patients begin receiving nutrition 13.2 hrs after admission. It is well known that critically ill patients have frequent interruptions in feeding administration for various reasons and that why those patients do not reach their nutritional goals (Elpern et al. 2004). However, delivery of nutrition by the enteral route may be subject to a variety of barriers, more than the parenteral route.

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 - MCT* to decrease potential for fat malabsorption⁴
 - Peptides to help manage diarrhoea^{5,6}
- ω -3 fatty acids to help manage inflammation^{7,8}
- Hypercaloric and high protein to help maintain lean body mass⁵

*Medium Chain Triglycerides



1. Khoshoo V et al. Incidence of Gastroesophageal Reflux with Whey and Casein-Based Formulas in Infants and in Children with Severe Neurological Impairment. *J Ped Gastroent Nutr.* 1996, 22:48-55. 2. Fried MD et al. Decrease in gastric emptying time and episodes of regurgitation in children with spastic quadriplegia fed a whey-based formula. *J Ped.* 1992;120:569-572. 3. Khoshoo V and Brown S. Gastric emptying of two whey-based formulas of different energy density and its clinical implication in children with volume intolerance. *Eur J Clin Nutr.* 2002, 56:1-3. 4. R.H.Rolandelli, J.R. Ullrich. Lipids and Enteral Nutrition. In: *Clinical Nutrition: Enteral and tube feeding.* J.L. Rombeau, R.H. Rolandelli, W.B. Saunders Company. 1997. 5. S. A. McClave et al. Guidelines for the Provision and Assessment of Nutrition Support Therapy in the Adult Critically Ill Patient: Society of Critical Care Medicine (SCCM) and American Society for Parenteral and Enteral Nutrition (A.S.P.E.N.) *Journal of Parenteral and Enteral Nutrition / Vol. 33, No. 3, May/June 2009.* 6. Meredith JW et al. Visceral protein levels in trauma patients are greater with peptide diet than with intact protein diet. *J Trauma* 1990, 30,825-829. 7. Calder P. n-3 Fatty acids, inflammation, and immunity—Relevance to postsurgical and critically ill patients. *Lipids.* 2004, 12:1147-1161. 8. Mayer K, Seeger W. Fish oil in critical illness. *Curr Op in Clinical Nutrition and Metab Care.* 2008.

These barriers include:

- Haemodynamic instability;
- Gut dysfunction;
- Gastric Retention;
- Ileus;
- Surgery;
- Tube feeding location;
- Many procedures and diagnostic tests in ICU;
- Radiological exams;
- Laboratory exams;
- Pharmacology gastroparesis; and
- The necessity to stop enteral infusion for patient mobilisation (McClave et al. 1999).

Importance of Utilising Strict Protocol

Nutrition is often prescribed by the physician and frequently, physicians fail to notice or realise that the prescribed amount of nutrition has not been administered, or if the patient has some intolerances. The success of enteral tube feeding depends on if the institution has a nutritional management protocol. Marked improvements in nutritional delivery can be achieved by implementing simple rules; such as efficient early placement of enteral tubes when patients arrive in the ICU, delivery of enteral nutrition as soon as possible, and limiting interruptions in feeding administration (Binnekade et al. 2005).

We are completely agreement with the Canadian guidelines on nutritional support. However, we think that based in our experiences, the use of semi-elemental formulas, improve the nutritional requirements earlier than polymeric formulas.

Glutamine

A number of trials utilising glutamine in critical illness have revealed that glutamine could improve infectious morbidity and mortality in critically ill patients (Goeters et al. 2002; Ziegler et al. 1992). Glutamine is now known to be “conditionally essential” in states of serious illness or injury (Lacey and Willmore 1990).

A hypothesis for these improvements is that the release of glutamine after stress provides a vital fuel source for enterocytes of the small bowel, rapidly dividing leukocytes and macrophages in the immune system, for its essential role in nucleic acid synthesis, and for acid-base homeostasis in the kidney (Uehara et al. 2005; Morrison et al. 2006; Wischmeyer 2007).

Conclusion

Based on research gathered from several papers, when treating critically ill patients with an intact GI tract, we prefer enteral over parenteral nutrition, and stress the importance of early, efficient and continuous delivery. Based on our experience, we think the use of semi-elemental formulas via enteral route let us target earliest nutritional requirements in critically ill patients. ■

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DRUG SAFETY

AGILIA DOSE RATE PUMPS WITH DRUG LIBRARIES FOR ENHANCED SAFETY

The Barts and The London NHS Trust has implemented more than 1,000 MC Agilia dose rate pumps from Fresenius Kabi since end 2008, in Intensive Care Units and all adult clinical areas. Mary Caddies, Senior Nurse for medical equipment, explains how drug libraries increase IV drug administration safety.



Marry Caddies, Senior Nurse.

“The choice of the Agilia dose rate pumps was based on cost effectiveness, usability, technical support, training and drug safety.”

► What were the main reasons behind the choice of Fresenius Kabi's dose rate infusion pumps?

The focus on intravenous drug administration and related errors has increased. Nurses are expected to administer much higher-risk drugs to patients. Errors can happen at any time – whether on the pharmacy side, the doctor prescribing, or the nurse programming or administering the drug. This risk has certainly increased over the years, and a lot of work has been done to try to reduce it. It's very important for us to purchase safe equipment for our Trust that will support the nursing staff and help them with their dose rate calculations. The choice of the Agilia dose rate pumps was based on cost effectiveness, usability, technical support, training and drug safety.

► What safety-enhancing factors, drove your choice of the MC Agilia dose rate pumps?

We also wanted all our new IV infusion pumps to be supported by drug safety software. We started with very few drugs, and have built up the Vigilant library.

► How did you draw up your drug list and implement it?

The actual set-up of it has to be hand-in-hand with Pharmacy and company. It has to be a partnership. You can't use what's been done before: every trust, right or wrong, has their own way of doing things. We have our own dedicated Pharmacists; and a monogram for every single drug that could be prescribed and administered in this Trust,

and staff have to use it. The other big barrier is that the concentrations of the drugs that we use aren't national or standardised – we have variable concentrations, which doesn't help support the software as readily as we'd like.

The drugs we're beginning to see – luckily it's the high-risk ones – are starting to have their concentrations standardised nationally and that's really beginning to help us. It doesn't matter which software and which device – if it's variable concentrations, we'll struggle a bit.

► How developed is your drug library?

We started with 16 high-risk drugs in the Volumat MC Agilia pumps, which was quite achievable. For the most recent project, we've employed a dedicated pharmacist on a consultancy basis. We've got about 110 drugs ready to load up into the Volumat MC Agilia pumps, which is the majority of them; and 30 into the Injectomat MC Agilia pumps, which is roughly 50%. That's a huge number of drugs to incorporate in the software.

“With Vigilant drug library, it's very easy for the nurses to select the drug they want.”

► Is the use of the drug libraries straightforward?

With Vigilant drug library, it's very easy for the nurses to select the drug they want. When you turn the pump on the drugs are there, listed alphabetically.

The nurse just scrolls down, selects one, reads the comments, makes sure it's the right drug, and programs the pump. If they make an error above or below the limits Pharmacy has set, they're warned.

This is why we like this device: the screen will actually “shout” at you: on-screen it says “Rate too high or too low”. Vigilant drug library instils more confidence in the users to do their work. If they do make a programming error, they are more likely to see it before commencing the infusion.

► How have your nursing staff responded to the pumps?

Our intensive-care units, by way of example, have both the Injectomat MC Agilia and the Volumat MC Agilia; and the staff have had full training. They are absolutely delighted and confident: they picked it up very quickly.

“If staff are familiar with and confident in using a device, they will use it safely.”

► Were you and the trainees satisfied with the training?

We did an evaluation of the initial training: the comments were hugely favourable, with everyone giving it between 95% and 100%. I think people have realised that training is key to getting the rollout right. If staff are familiar with and confident in using a device, they will use it safely. Fresenius Kabi's initial training probably exceeded our expectations.

Interview conducted by Paul Jones

NUTRITION CHALLENGES OF THE OBESE IN THE ICU



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Obese patients are a large and growing group in the ICU. Obese patients face a number of problems in the ICU: Length of stay is usually longer, the risk of infections and of pressure sores is higher, respiratory problems more frequent but mortality is usually similar to patients with lower BMI after risk adjustment. There is most likely a U-shaped association between outcome and BMI with a slightly higher risk of death in the very low BMI (e.g. $\leftarrow 18.5$) and the extremely obese III (BMI $\rightarrow 40$) whereas the risk is slightly lower in overweight and obese patients. Such a U-shaped association appears also to exist for risk of critical illness necessitating ICU admission. Patients with low and high BMI are over represented in hospitalised patients and even more in ICU patients as found in the nutritionDay project for wards and ICUs, as well as in a recent Canadian project.

Little attention has been given to nutrition of the obese in the ICU until recently. Many different concepts have been applied in obese critically ill patients. Partial starvation of these patients is one accepted nutritional strategy while another is to consider standard nutrition mandatory until recovery from critical illness is achieved. Special consideration should be given to the fact that many complications associated with obesity in the ICU, such as pneumonia, poor wound healing, pressure sores, and difficult weaning are typical complications of under- or overnutrition. The U-shaped association of complications indicates that optimal energy supply may be a critical factor for improved outcome.

Energy Consumption in the ICU

Energy consumption and thus energy needs are commonly determined with the use of a formula, only few ICUs routinely use indirect calorimetry to measure energy consumption. The Harris-Benedict equation, determined in 1918 by study of 239 healthy adults and 94 newborns, is the standard formula used in many institutions (Harris and Benedict, 1918). The range of weights covered was from 25 to 125 kg and the age from 21 to 70 years. Thus the formula is certainly representative for a mean population but not for patients with “disease related malnutrition” or the morbidly obese. The mean energy consumption of 25.7 Kcal.kg⁻¹ in men and 24.5 Kcal.kg⁻¹ in women is very near to the simple recommendation of 20-25 Kcal.kg⁻¹ in the acute state

and 25-30 Kcal.kg⁻¹ during recovery (Kreymann et al. 2006). Measurements in many groups of critically ill patients have challenged the use of the Harris-Benedict equation with the two formulae depending on gender. The deviation between measurement and calculation could be as large as 300-500 Kcal around the mean value (Faisy et al. 2003). Adding minute ventilation and body temperature to weight and height and excluding age and gender have improved the individual prediction slightly.

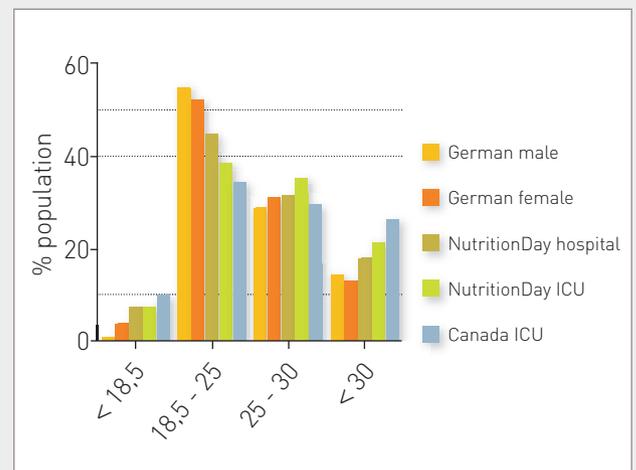


Figure 1. BMI groups in the standard German population and several groups of hospitalised patients

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- **Allow guidance of antibiotic therapy**^{3,4,5,6}
- **Help early detection of treatment failure**⁷

¹ Müller B et al. Crit Care Med 2000, 28(4): 977-983

² Harbarth S et al. Am J Respir Crit Care Med 2001, 164: 396-402

³ Christ-Crain M et al. The Lancet 2004, 363(9409): 600-607

⁴ Marc E et al. Arch Pédiatr 2002, 9: 358-364

⁵ Chromik AM et al. Langenbecks Arch Surg. 2006 Jun; 391(3): 187-94

⁶ Nobre V et al. Am J Respir Crit Care Med 2007 Dec 20; Epub ahead of print

⁷ Luyt CE et al. Am J Respir Crit Care Med 2005, 171(1): 48-53



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- Thus most recommendations have included the simple formula $25 \text{ Kcal.kg}^{-1}.\text{day}^{-1}$ to determine energy needs. Weight is usually actual weight but some authors have advocated the use of ideal or adjusted body weight for patients with an increased BMI.

Age should always be considered as energy consumption decreases by 15-20% between the age of 40 and 80 years (Poehlman 1992). Another factor that may have a dynamic effect on energy consumption is disease activity and shock. Energy consumption decreases in general when disease is associated with a compromised cardio-circulatory function such as in severe sepsis or septic shock (Kreyman et al. 1993).

Energy Deficit in the ICU

A substantial energy deficit has been found in many ICU patients that have been followed prospectively with either indirect calorimetry or assessed in comparison with accepted standards. The largest energy deficit accumulates during the first week of ICU stay (Dvir, et al. 2006; Krishnan, et al. 2003; Villet et al. 2005). An energy deficit above 5000 Kcal was not uncommon during the first week and has been associated with an increased risk of complications such as infections, renal failure and pressure sores. The development of an energy deficit has never been followed specifically in obese patients.

A surprising relation between BMI and energy supply has been found in a large multi-centric trial. Patients with a BMI < 20 received 990 Kcal in 24 hours and this amount was not much larger in those with a BMI > 40 with 1050 Kcal in 24 hours. All other BMI groups were between these two values suggesting that all patients received the same amount of nutrition regardless of BMI (Alberda, et al., 2009). The amount of nutrients given was slightly higher in the nutritionDay ICU project (www.nutrition-day.org)

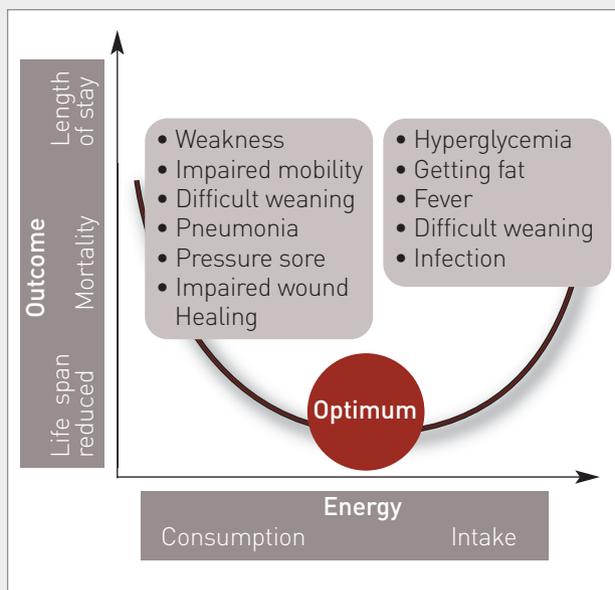


Figure 2. Association between energy intake and complications

“Thus most recommendations have included the simple formula $25 \text{ Kcal.kg}^{-1}.\text{day}^{-1}$ to determine energy needs.”

where more than 50% of patients in all BMI categories received more than $20 \text{ Kcal.kg}^{-1}.\text{day}^{-1}$ based on ideal body weight. The variability in the amount of energy given was high and similar for all groups, indicating again that there is great uncertainty about the optimal amount of nutrients.

Overnutrition in the ICU

Overnutrition is probably actually much less frequent nowadays because the deleterious effects of hyperalimentation such as fatty liver, respiratory failure and difficult to control hyperglycemia are well known. It has been shown that any increase in energy intake above measured resting energy expenditure induces an increase in weight in parallel with fat accumulation and without any beneficial effect on protein loss. Clinical signs of overnutrition should be appreciated when calorimetry is not available to tailor nutrition care.

Nutrition and Metabolic Abnormalities in Obese Patients

Obesity is often associated with the metabolic syndrome with increased insulin levels and a proinflammatory state. Traumatized obese patients have a decreased efficiency in protein synthesis, a larger protein breakdown and a reduced fat oxidation compared with normals. Lipolysis was reduced and free fatty acids levels high indicating a block in the utilisation of fat as fuel. Thus endogenous protein may serve as fuel despite the large fat stores.

Morbidly obese patients have frequently decreased levels of vitamin B6, C and D (Aasheim et al. 2008). Moreover, many of these patients have used special diets or have repeatedly tried a massive reduction in nutrient intake leading to additional deficits of vitamins, electrolytes and essential nutrients. These patients, especially if weight loss in the last month is also reported, should be considered as malnourished and have probably a decreased lean body mass despite a high BMI.

Refeeding syndrome should always be considered when artificial nutrition is started in patients with specific risk profile, such as several days of low nutrient intake, weight loss within the last 3-6 months, electrolyte abnormalities, history of alcohol misuse or chronic medication with insulin, antacids or diuretics (NICE 2006).

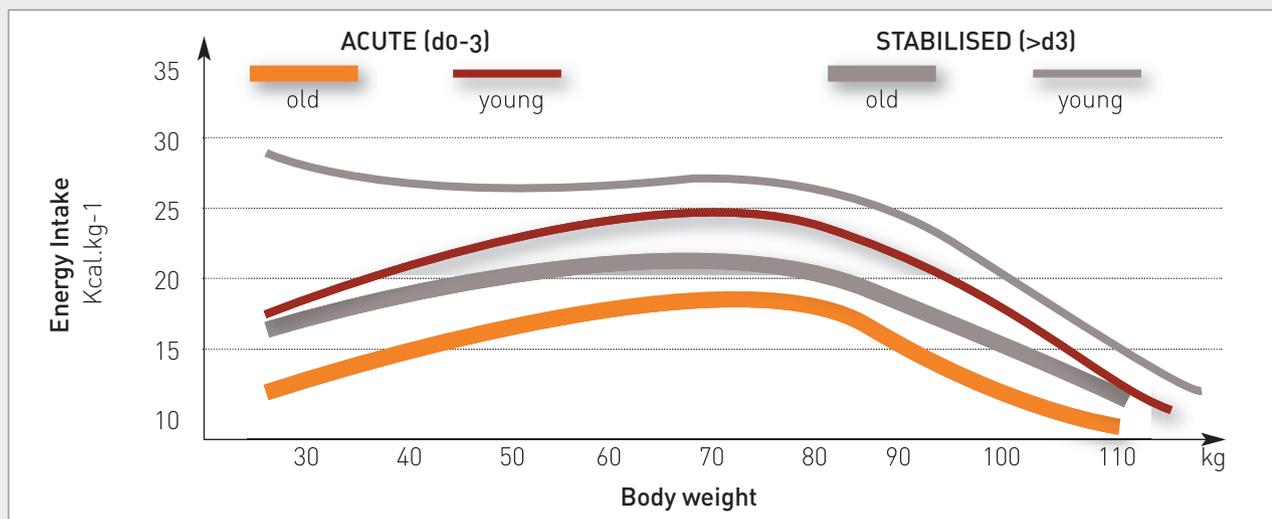


Figure 3. A conceptual approach to nutrition support of energy supply vs actual body weight

Artificial Nutrition in Obese Critically Ill

We suggest that patients at the extremes of BMI should receive safe and proper nutrition care based a simple concept as illustrated in figure 3. For obese patients the three major elements are an early start of nutrition care, careful tailoring of the amount of energy and a substantially increased amino acid supply.

Nutrition care should start early e.g. within 24 hours of admission to avoid large energy deficits in these patients with a high probability of nutrition deficits and abnormalities before admission to the ICU. Energy intake should be gradually increased to reduce the risk of re-feeding syndrome and to be able to assess tolerance. Measured or estimated energy needs should be met by day three after adequate stabilisation. Estimation of energy needs in the very low BMI group should be based on actual body weight and increased carefully to ideal body weight if well tolerated whereas the energy estimates for the obese patients should be based on ideal body weight. Because large inter-individual differences in energy needs are well known, clinical signs of overnutrition should be searched. The problem of the accumulation of a large energy deficit can be prevented by the early start of nutrition support and an effort to reach soon a reasonable target. In very old patients the amount of energy should be reduced compared with recommendations by 10-20 percent.

Specific attention should be given to a sufficient provision of protein. The amount of protein should be increased to about 2g.kg-1.day-1 to compensate for the metabolic abnormality of increased and preferential protein breakdown in injured obese patients. I would suggest again ideal body weight as the reference for calculations. Unfortunately, there are actually not sufficient choices of enteral and parenteral industrial nutrition solutions that satisfy the two conditions of moderate energy supply with a high protein content.

Conclusion

In summary, nutritional care of the obese ICU patient will be a challenge for the future as this group is vulnerable and will further increase in the next years. Recommendations are based on the synthesis of a puzzle of elements and the proposed strategy should be prospectively evaluated in different settings. ■

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NUTRITIONAL SUPPORT IN CRITICALLY ILL OBSTETRIC PATIENTS



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Critically ill pregnant patients (CIPP) are not common in intensive care units (ICU) compared to other groups of patients. However, a considerable number of admissions of CIPP to the ICU are seen in developing countries (Briones 2006). These patients have a higher metabolic basal rate (MBR) due to a combination of the pregnancy itself (which normally increases the MBR) and the critical condition. Nutritional support must be initiated as soon as the patients are haemodynamically stable and needs to be focused on both maternal and fetal requirements. Suboptimal nutritional support can decrease fetal growth and increase the risk of death for both mother and fetus.

Nutritional assessment in complicated pregnancy includes evaluation of weight and height, as well as biochemical, clinical and dietetic variables.

Weight and height are the main variables to evaluate the nutritional state of pregnant women. The gain of weight recommended during pregnancy is determined by the pre-pregnancy body mass index (BMI): BMI= pre-pregnancy weight kg/height m², which is important to classify the nutritional state (BMI= ≤18.5 under weight, 18.6-24.9 normal weight, 25-29.9 overweight, ≥30 obesity). Under ideal conditions the BMI must be determined at the beginning of pregnancy. However, in CIPP it is difficult to calculate the weight before pregnancy; therefore it is suggested to use the proportion of ideal body weight (IBW) according to the gestational age (%IBW: the patient has to be 90-110% of the ideal weight according to the gestational age during the entire pregnancy) (Villazon and Arenas 2008; De Legge and Drake 2007).

Biochemical evaluation: During pregnancy, specifically in CIPP it is recommended to determine cholesterol, triglycerides, glucose, haemoglobin, albumin,

transferin, pre-albumin, nitrogen balance and ureic nutritional balance. Dislipidemia (high values of cholesterol and triglycerides in blood) may occur because of the pregnancy or due to malnutrition. The presence of obesity and dislipidemia and/or hyperglycemia produces a metabolic syndrome.

Mexico now occupies the second place worldwide for obesity: seven out of ten women are obese. On the other hand, few data are available on the prevalence of gestational diabetes and metabolic syndrome in obstetric patients (Kruse 2005). Additionally, it is important to consider the biochemical variables to calculate the amount of micro and macronutrients, which have to be properly distributed.

Recommended total gain weight	
BMI (←19.8)	12.5 – 18 kg
BMI (19.8 – 26)	11.5 – 16 kg
BMI (26 – 29)	7 – 11.5 kg
BMI (→29)	6 kg
Twins	16 – 20 kg

Table 1. Recommended gain of weight in pregnancy according to body mass index (BMI)



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Picture 1. Pregnant woman in the OR. (Picture courtesy of Paul Schultz)

Physical examination must be performed according to the main diagnosis and focused on their effect on the nutritional state and/or the integrity of the gastrointestinal tract (Sobotka et al. 2004). An advantage of giving nutritional support in CIPP is the absolute control of quality, quantity and food composition (Simon et al. 2003).

Diet should be considered an immediate intervention, either oral, enteral, total parenteral nutrition (TPN) or a combination of these. If diet should include at least 75% of daily requirements in a critically ill patient, in CIPP it is important to ensure 100% of their daily requirements to obtain an optimal weight gain (Table 1).

Calculation of Daily Requirements

The main diagnosis of the CIPP should be taken into account to ensure a proper nutritional diagnosis. Due to the difficulties in determining weight and height at the ICU in CIPP, it is recommended to use specific formulas (which include the actual body weight) to calculate energy and protein requirement according to the stress factor described in Table 2.

	Protein	Energy
Mild	0.8 g/kg/day	20 – 25 kcal/kg/day
Moderate	1.0 – 1.5 g/kg/day	20 – 25 kcal/kg/day
Severe	1.5 – 2.5 g/kg/day	30 – 35 kcal/kg/day
Critically ill pregnant woman	1.7 g/kg/day or less, depending on renal function	Depends on the previous nutritional state, usually from 25 - 40 kcal/kg/day

Table 2. Fast equation to calculate energy and proteins according to the metabolic stress factor.

Nutritional Support

There is no difference in indications between CIPP and those pregnant women who are not in a critical condition. If the gastrointestinal tract is intact, enteral nutrition should be started as soon as possible. If there is a contraindication to use the gastrointestinal tract then a TPN is indicated, mainly if the patient is at high risk of malnutrition (Kruse 2005; Sobotka et al. 2004). The combination of TPN with enter-

al nutrition is recommended if the patient cannot meet the energy requirements, but few data are available regarding the benefit of using a combined therapy (Simon et al. 2003).

Routes of Nutrition

The best route to give an adequate nutrition in a CIPP depends on the severity of the case. The enteral route is the first choice if the gastrointestinal track is intact and the components of the diet

“If diet should include at least 75% of daily requirements in a critically ill patient, in CIPP it is important to ensure 100% of their daily requirements to obtain an optimal weight gain.”

will provide the amount of energy and proteins required according to the severity of the case. When a CIPP has a gastrointestinal dysfunction and/or the enteral nutrition will not fulfil the energy and protein requirements, then an intravenous route should be considered (Villazon and Arenas 2008; Sobotka et al. 2004).

Conclusion

Nutritional support in CIPP should be managed by a professional nutritionist as part of the ICU team to treat and follow the nutritional progress of the patient. It is very important to start nutritional support in CIPP at the ICU as soon as possible, due to the high daily requirements of energy and proteins that pregnancy demands. Nutritional support should promote fetal growth as well as appropriate weight gain of the mother. ■

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ANAESTHESIA UNITS

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RECOMMENDATIONS

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ECRI Institute is pleased to provide readers of ICU Management with sample information on Basic Performance Anaesthesia Units from its Healthcare Product Comparison System (HPCS), which contains over 280 reports. The HPCS reports contain extensive information about the technology, its purpose, its principles of operation, stage of development specifications and reported problems. The Anaesthesia Units comparison charts include ECRI Institute's 'Recommended Specifications' (generic templates) which can be used for comparison and tendering purposes. The comparative tables overleaf are extracted from ECRI's 2005 database and have additionally been reviewed and updated by the respective manufacturers.

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SUPPLIER	ECRI INSTITUTE'S RECOMMENDED SPECIFICATIONS	
MODEL	Basic Performance Anaesthesia Units<1>	Zeus IE
WHERE MARKETED		Worldwide, except USA
FDA CLEARANCE		No
CE MARK (MDD)		Yes
CONFIGURATION		Mobile, ceiling
PIPELINE GAS INLETS	All	3 (O ₂ , N ₂ O, air)
GAS CYLINDER YOKES	O ₂	3 (O ₂ , N ₂ O, air)
VAPORIZERS, AGENTS	Isolfurane, halothane, enflurane, desflurane, sevoflurane	Sevoflurane, isoflurane, desflurane
Type		Direct injection system
Number	1	2 removable
Interlock	Yes (if >1 vaporizer)	Electronic
O₂ FAIL-SAFE	Audible, visual, N ₂ O shutoff	Audible and visual alarm, N ₂ O lock and air delivery
HYPOXIC MIXTURE FAIL-SAFE	Yes (methods vary)	Electronic O ₂ ratio controller
AUTOMATIC VENTILATOR	Yes	Yes
Bellows, size		Universal
Type		Blower
Primary controls		
Ventilation modes	Manual, spontaneous, VCV	Manual/spontaneous, volume mode constant flow, volume mode autflow with or without synchronization and pressure support, pressure mode with or without synchronization and pressure support; CPAP/pressure support
Tidal volume; Range, cc	Range: 50-1,200	Yes; Range: 20-1,500
Minute volume; Range, L/min	Range: >20	Yes; Range: Up to 40
Frequency, bpm	60	80
Inspiratory flow, L/min		180 maximum
IE ratio		4:1 to 1:4
Inspiratory pause	Optional	20-50% Ti
Pressure limit, cm H₂O	Adjustable, <70 preferred	Up to 70 hPa
PEEP, cm H₂O	0-20	0 to 35 hPa
Other controls		Pmax (pressure limit), Slope time, inspiratory time, trigger, pressure support level
System checks	Pre-use vent, gas supply, ongoing system	Fully automated self-diagnostics with graphical help, leakage test and leakage assistant
MONITORS		
Airway pressure	Yes	Yes
High-pressure alarm	Yes	5-100cm H ₂ O
Subatmospheric pressure alarm	Yes	≤10 cm H ₂ O
Continuing pressure alarm	Yes	High PEEP
Low pressure/apnea	Yes	Yes
Other pressure alarms	Optional	Apnea ventilation (in pressure support), Paw not attained
Expiratory volume/flow	Yes	Yes
Rate alarm		No
Apnea alarm	Yes (method may vary)	Yes
Reverse-flow alarm		Yes
High/low minute volume		Yes
High/low flow		No
Other expiratory alarms		Sensor disconnect/fail (inspiratory and expiratory), air trapping, tube leak
O₂ concentration	Yes	Inspiration/expiration
Response time, sec	<30	<0.5
CO₂ concentration	Optional	Yes
Apnea alarm	Required (if CO ₂ monitoring is integral)	Yes
N₂O	No	Yes
Agent monitors; Type of agents	No; N/A	Yes; Sevoflurane, enflurane, halothane, isoflurane, desflurane
ECG	No	Yes
Noninvasive BP	No	Yes
Invasive BP	No	Yes; up to 10
Temperature	No	Yes; up to 2
Pulse oximeter	No	Yes
Other monitors	None	EEG (BIS), NMT
DISPLAYS: Number; Type	Yes: 1	Yes: 1; 17" color wide screen (flat panel) with resistive touch
BACKUP BATTERY	Required	Yes
Type		Lead-acid gel
Use per charge, hr	0.5	0.5 - 1.5 depending on the setup
OTHER SPECIFICATIONS		Electrically driven turbine ventilator with circle flow; fresh-gas decoupled; compliance compensated; compact breathing system; electronic export of all gas delivering data; closed system; feedback control for FiO ₂ and anesthetic agent; direct injection of volatile agent; fully integrated patient monitoring; full remote control of IV pumps; 360° pivotable, height-adjustable and tilttable screens; central brake.
Footnotes:	<1> These recommendations are the opinions of ECRI Institute's technology experts. ECRI Institute assumes no liability for decisions made based on this data.	Data Footnotes: <*> Inspiratory and expiratory values for all measured gases; trends for all; measured gases; curve display for Paw; numeric display for MEAN, PEAK, PLAT, PEEP; curve display for flow (inspiratory/expiratory); numeric display for MV, Vt, rate, MV/Leak, Cpat; trends for MV and Cpat; bar graphs for Vt and Paw; low-flow wizard; econometer; optional curve display for SpO ₂ (plethysmogram); optional numeric display for SpO ₂ and heart rate; optional trend for SpO ₂ and pulse; optional loops (p/V-loop and flow/V-loop).



Primus IE	Fabius GS Premium	Fabius MRI	Aestia MRI	Aespire View
Worldwide, except USA	Worldwide	Worldwide	Worldwide	Worldwide
No	Yes	Yes	Yes	Yes
Yes	Yes	Yes	Yes	Yes
Trolley, ceiling, wall	Trolley	Trolley	Mobile with locking casters (footrest)	Mobile with locking casters
3 (O2, N2O, air)	3 (O2, air, N2O), 2 optional (O2, air)	3 (O2, air, N2O)	4 optional (O2, N2O, air)	3 (O2, N2O, air)
2 (O2, N2O)	3 (2 O2, air or N2O)	3 (O2, air, N2O)	4 optional (O2, N2O, air, CO2, heliox)	3 (O2, N2O, air)
Sevoflurane, enflurane, halothane, isoflurane, desflurane	Sevoflurane, enflurane, halothane, isoflurane, desflurane	Sevoflurane, enflurane, halothane, isoflurane	Sevoflurane, enflurane, halothane, isoflurane	Sevoflurane, enflurane, halothane, isoflurane, desflurane
Variable bypass, removable mount	Variable bypass, removable mount	Variable bypass, removable mount	Tec 6 Plus and Tec 7: temperature, flow, pressure compensated, EZ Fill	Tec 6 Plus and Tec 7: temperature, flow, pressure compensated, EZ Fill
2 removable	2 (Dräger Interlock; US autoexclusion system)	2 (Dräger Interlock; US autoexclusion system)	2	2
Yes	Yes	Yes	Yes	Yes
Yes, O2 emergency delivery	Yes	Yes	Pneumatic	Pneumatic
Electronic O2 ratio controller	O2 ratio controller	O2 ratio controller	Mechanical link	Mechanical link
Yes	Yes	Yes	7900 Smartvent	7900 Smartvent
Universal	Universal	Universal	1,500 mL	1,500 mL
Piston	Piston	Piston	Ascending, standing, multibreath	Ascending, standing, multibreath
Manual/spontaneous; volume and pressure controlled ventilation with synchronization; optional pressure support in volume and pressure ventilation and pressure support mode; optional Volume Mode AutoFlow	Manual/spontaneous, volume, pressure, pressure support, optional SIMV	Manual/spontaneous, volume, pressure, pressure support, SIMV	VCV, PCV, SIMV-VC, SIMV-PC, PSVPro, CPAP	VCV, PCV, SIMV-PC, PSVPro, CPAP, PCV-VG
Yes; Range: 5-1,400	Yes; Range: 20-1,400	Yes; Range: 20-1,400	1,500 mL; Range: 20-1,500	1,500 mL; Range: 20-1,500
Yes; Range: Up to 50	Yes; Range: Up to 50	Yes; Range: Up to 50	Yes; Range: 0.08-120	Yes; Range: 0.08-120
3-100	4 to 60	4 to 60	4-100	4-100
0.1-150	10-75 in PC / 10-85 in PS and SIMV	10-75 in PC / 10-85 in PS and SIMV	1-120	1-120
Tinsp 0.2 to 6.7 [s] (max. 5:1 to 1:99 I:E)	4:1 to 1:4	4:1 to 1:4	2:1 to 1:8	2:1 to 1:8
0-60% Ti	0-50% Ti	0-50% Ti	0-60% Ti	0-60% Ti
Up to 70	Up to 70	Up to 70	12-100	12-100
0-20, max. (P _{MAX} - 10 hPa)	0-20	0-20	4-30 electronic	4-30 electronic
Volume/pressure control, manual, spontaneous, SIMV, trigger, ramp time, optional pressure support	Pmax (pressure limit), inspiratory flow (pressure control), inspiratory pause (Tip:Ti)	Pmax (pressure limit), inspiratory flow (pressure control), inspiratory pause (Tip:Ti)	Float-type flowmeters, breath-to-breath tidal volume compensation	Float-type flowmeter, breath-to-breath tidal volume compensation
Manual checklist, fully automated self-test	Semiautomatic leak and compliance check, self-diagnosis of processor	Semiautomatic leak and compliance check, self-diagnosis of processor	Manual pre-use test, ventilator self-test	Manual pre-use test, ventilator self-test
Yes	Yes	Yes	Yes	Yes
5-99 cm H2O	5-99 mbar	5-78 mbar	Adjustable	Adjustable
<-7 cm H2O	-8 cm H2O	-8 cm H2O	Yes	Yes
High PEEP, Continuous Pressure	Above pressure threshold for >15 sec	Above pressure threshold for >15 sec	Yes	Yes
Apnea pressure, P _{insp} not attained	Below pressure threshold for >15 sec	Below pressure threshold for >15 sec	Yes	Yes
Apnea ventilation (in Pressure Support),	High PEEP, apnea, low threshold	High PEEP, apnea, low threshold	Not specified	PEEP high
Yes; inspiratory flow information also available	Yes	Yes	Yes	Yes
No	No	No	No	No
Yes; pressure, flow, and CO2 apnea alarms available	Yes	Yes	Yes	Yes
No (covered by integrated patient gas monitoring)	Yes	Yes	Yes	Yes
Yes	Low	Low	Yes	Yes
No. Instead: optional fresh gas economizer available	No	No	Yes	Yes
Sensor disconnect/fail (inspiratory and expiratory)	Sensor disconnect	Sensor disconnect	Circuit leak	Circuit leak
Inspiratory/ expiratory	Yes	Yes	Yes<1>	Yes<1>
<-0.5	<25	<25	<35	<35
Inspiratory/ expiratory	Yes with optional Scio or Vamos	No	Optional	Optional
Yes; pressure, flow, and CO2 apnea alarms available	Yes with optional Scio or Vamos	No	Yes	Yes
Inspiratory/ expiratory	Yes with optional Scio or Vamos	No	Yes	Yes, with above
Inspiratory/ expiratory; Sevoflurane, enflurane, halothane, isoflurane, desflurane	Yes with optional Scio or Vamos	No	Yes; All 5, plus mixtures<2>	Yes, with above; All 5, plus mixture
No	No	No	3-lead<2>	3-, 5-, or 12-lead
No	No	No	15 to 260 mm Hg<2>	15 to 260 mm Hg
No	No	No	-40 to 320 mm Hg<2>	-40 to 320 mm Hg
No	No	No	No	°C or °F, up to 4
No	No	No	Yes, Datex-Ohmeda	Nellcor/Datex-Ohmeda
None specified	None specified	None specified	None	Respiration, NMT<2>
Yes: 1; TFT color flat panel	Yes: 1; TFT black/amber or color flat panel (16.5 cm [6.5"])	Yes: 1; TFT color flat panel (16.5 cm [6.5"])	7900 Smartvent: 1; LCD monochrome	7900: 1; Full color 12.1" (31cm)
Yes	Yes	Yes	In ventilator	In ventilator
Lead-acid gel	Sealed lead-acid	Sealed lead-acid	Sealed lead-acid	Sealed lead-acid
>0.5	0.75	0.75	0.5 maximum load	0.5
Electrically driven piston ventilator; fresh-gas decoupled; compliance compensated; compact breathing system; electronic export of fresh-gas data to an anesthesia information system; warmed breathing system; integrated gas analyzer.	Electrically driven ventilator; fresh-gas decoupled; compliance compensated; compact breathing system; electronic export of fresh-gas data to an anesthesia information system; warmed breathing system.	Electrically driven ventilator; fresh-gas decoupled; compliance compensated; compact breathing system; electronic export of fresh-gas data to an anesthesia information system; warmed breathing system.	Gauss alarm; vaporizer storage brackets; breathing system/bag alarms; number of cylinder yokes and gases; auxiliary common gas outlet; Bain module; O2 flowmeter; IV poles; additional shelf; CastrGard; integrated suction. Meets requirements of ASTM F180, CSA, EN 740, JIS, and UL.	2.7 liter volume in vent mode; vaporizer storage brackets; breathing system/bag alarms; number of cylinder yokes and gases; auxiliary common gas outlet; O2 flowmeter; IV poles; CastrGard; integrated suction. Meets requirements of ASTM F180, CSA, EN 740, JIS, and UL.
Model Footnotes: The device is equipped with RFID technology. This technology enables device dedicated accessories to communicate with the Primus IE to display compatibility, exchange times and protect against mismatch. Data Footnotes: <see * on the Zeus IE section>.			Data Footnotes: <1> The Datex-Ohmeda Link 25 hypoxic guard precludes setting hypoxic O2 flow ratios; DIS interface to Datex-Ohmeda MRI patient monitor. <2> With GEHC Datex-Ohmeda MRI patient monitor.	Data Footnotes: <1> Available with Datex-Ohmeda S/5 AM anesthesia monitoring system and CARESCAPE B850 monitoring system. <2> Cardiac output, SvO2, spirometry, EEG, DIS interface to other monitors.



SUPPLIER	ECRI INSTITUTE'S RECOMMENDED SPECIFICATIONS		
MODEL	Basic Performance Anesthesia Units <1>	Aisys Carestation	Avance
WHERE MARKETED		Worldwide	Worldwide
FDA CLEARANCE		Yes	Yes
CE MARK (MDD)		Yes	Yes
CONFIGURATION		Mobile with locking casters	Mobile with locking casters
PIPELINE GAS INLETS	All	3 (O2, air, optional N2O)	3 (O2, air, optional N2O)
GAS CYLINDER YOKES	O2	2 (O2, optional N2O, air)	2 (O2, optional N2O, air)
VAPORIZERS, AGENTS	Isoflurane, halothane, enflurane, desflurane, sevoflurane	Sevoflurane, enflurane, halothane, isoflurane, desflurane	Sevoflurane, enflurane, halothane, isoflurane, desflurane
Type		Aladin cassette	Tec 6 Plus and Tec 7: temperature, flow, pressure compensated, EZ Fill
Number	1	1 active vaporiser position. 2 storage bays for inactive vaporisers	2
Interlock	Yes (if >1 vaporizer)	Yes	Yes
O2 FAIL-SAFE	Audible, visual, N2O shutoff	Electronic	Electronic
HYPOXIC MIXTURE FAIL-SAFE	Yes (methods vary)	Electronic	Electronic
AUTOMATIC VENTILATOR	Yes	7900 Smartvent	7900 Smartvent
Bel lows, size		1,500 mL	1,500 mL
Type		Ascending, standing, multibreath	Ascending, standing, multibreath
Primary controls			
Ventilation modes	Manual, spontaneous, VCV	VCV, PCV, SIMV-VC, SIMV-PC, PSVPro, CPAP, PCV-VG, End tidal Control	VCV, PCV, SIMV-VC, SIMV-PC, PSVPro, CPAP, PCV-VG
Tidal volume; Range, cc	Range: 50-1,200	1,500 mL; Range: 20-1,500	1,500 mL; Range: 20-1,500
Minute volume; Range, L/min	Range: >20	Yes; Range: 0.08-120	Yes; Range: 0.08-120
Frequency, bpm	60	4-100	4-100
Inspiratory flow, L/min		1-120	1-120
IE ratio		2:1 to 1:8	2:1 to 1:8
Inspiratory pause	Optional	0-60% Ti	0-60% Ti
Pressure limit, cm H2O	Adjustable, <70 preferred	12-100	12-100
PEEP, cm H2O	0-20	4-30 electronic	4-30 electronic
Other controls		Electronic mixer breath-to-breath tidal volume compensation	Electronic mixer breath-to-breath tidal volume compensation
System checks	Pre-use vent, gas supply, ongoing system	Electronic, semiautomatic	Electronic, semiautomatic
MONITORS			
Airway pressure	Yes	Yes	Yes
High-pressure alarm	Yes	Adjustable	Adjustable
Subatmospheric pressure alarm	Yes	Yes	Yes
Continuing pressure alarm	Yes	Yes	Yes
Low pressure/apnea	Yes	Yes	Yes
Other pressure alarms	Optional	Not specified	Not specified
Expiratory volume/flow	Yes	Yes	Yes
Rate alarm		No	No
Apnea alarm	Yes (method may vary)	Yes	Yes
Reverse-flow alarm		Yes	Yes
High/low minute volume		Yes	Yes
High/low flow		Yes	Yes
Other expiratory alarms		Circuit leak	Circuit leak
O2 concentration	Yes	Yes<1>	Yes<1>
Response time, sec	<30	<35/breath-to-breath	<35/breath to breath
CO2 concentration	Optional	Optional	Optional
Apnea alarm	Required (if CO2 monitoring is integral)	Yes	Yes
N2O	No	Yes, with above	Yes, with above
Agent monitors; Type of agents	No; N/A	Yes, with above; All 5, plus mixture	Yes, with above; All 5, plus mixture
ECG	No	3-, 5-, or 12-lead	3-, 5-, or 12-lead
Noninvasive BP	No	15 to 260 mm Hg	15 to 260 mm Hg
Invasive BP	No	-40 to 320 mm Hg	-40 to 320 mm Hg
Temperature	No	°C or °F up to 4	°C or °F up to 4
Pulse oximeter	No	Nellcor/Datex-Ohmeda	Nellcor/Datex-Ohmeda
Other monitors	None	Respiration, NMT, ENTROPY<2>	Respiration, NMT, ENTROPY<2>
DISPLAYS: Number; Type	1	One 30.5 cm (12"); optional 30.5 cm (12"), 38.1 cm (15"), 43.2 (17"); Full color 12.1" (31cm)	One 30.5 cm (12"); optional 30.5 cm (12"), 38.1 cm (15"), 43.2 (17"); Full color 12.1" (31cm)
BACKUP BATTERY	Required	Yes	Yes
Type		Sealed lead-acid	Sealed lead-acid
Use per charge, hr	0.5	0.5 maximum load	0.5 maximum load
OTHER SPECIFICATIONS		2.7 liter volume in vent mode; vaporizer storage brackets; breathing system/bag alarms; number of cylinder yokes and gases; auxiliary common gas outlet; O2 flowmeter; IV poles: CastrGuard; integrated suction. Meets requirements of ASTM F180, CSA, EN 740, JIS, and UL.	2.7 liter volume in vent mode; vaporizer storage brackets; breathing system/bag alarms; number of cylinder yokes and gases; auxiliary common gas outlet; O2 flowmeter; IV poles: CastrGuard; integrated suction. Meets requirements of ASTM F180, CSA, EN 740, JIS, and UL.
Footnotes:	<1> These recommendations are the opinions of ECRI Institute's technology experts. ECRI Institute assumes no liability for decisions made based on this data.	Data Footnotes: <1> Available with Datex-Ohmeda S/5 AM anesthesia monitoring system and CARESCAPE B850 monitoring system. <2> Cardiac output, SvO2, spirometry, EEG, DIS interface to other monitors.	Data Footnotes: <1> Available with Datex-Ohmeda S/5 AM anesthesia monitoring system and CARESCAPE B850 monitoring system. <2> Cardiac output, SvO2, spirometry, EEG, DIS interface to other monitors.

	MEDEC	MEDEC	MEDEC	MEDEC	SPACELABS HEALTHCARE <1>	SPACELABS HEALTHCARE <1>	SPACELABS HEALTHCARE <1>
	Neptune	Saturn Evo Color	Saturn Evo Standard	Saturn Evo advanced Touch (screen on the side)	BleaseFocus	BleaseGenius/Genius MRI	BleaseSirius
	Worldwide	Worldwide	Worldwide	Worldwide	Worldwide	Worldwide	Worldwide
	Submitted	Submitted	Submitted	Submitted	No	Yes	Yes
	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Mobile on wheels	Mobile on wheels	Mobile on wheels	Mobile on wheels	Mobile /Pendant	Mobile, wall	Mobile/Pendant
	3 (O2, N2O, air)	3	3 (O2, N2O, air)				
	2 (O2, N2O)	2 (O2, N2O)	2 (O2, N2O)	2 (O2, N2O)	4 maximum	2 maximum	4 maximum
	Sevoflurane, enflurane, halothane, isoflurane, desflurane	Sevoflurane, isoflurane, halothane, enflurane	Sevoflurane, isoflurane, halothane, enflurane	Sevoflurane, isoflurane, halothane, enflurane			
	Not specified	Not specified	Not specified	Not specified	Plenum-type variable bypass, fully compensated	Plenum-type variable bypass, fully compensated	Plenum-type variable bypass, fully compensated
	2	3	3	3	2 maximum	2 maximum	2 maximum
	Yes	Yes	Yes	Yes	Fully compatible	Fully compatible	Fully compatible
	Electronic and pneumatic alarm system	Multigas cutoff, full alarms	Alarm	Multigas cutoff, full alarms			
	Yes	Yes	Yes	Yes	Gear-driven ratio system	Gear-driven ratio system	Gear-driven ratio system
	Yes	Yes	Yes	Yes	Blease700/900	2200	Blease700/900
	1 for neonate to adult	Adult/pediatric	Adult/pediatric	Adult/pediatric			
	Horizontal bag in bottle	Ascending, bag in bottle	Ascending, bag in bottle	Ascending, bag in bottle			
	CMV, manual, spontaneous, PCV	CMV, manual, spontaneous, PCV, SIMV, PS	CMV, manual, spontaneous, PCV, SIMV	CMV, manual, spontaneous, PCV, SIMV, PS	Adult, Pediatric, CMV, PPCV, SIMV+PSV, AdPSV	Adult, Pediatric, CMV	Adult, Pediatric, CMV, PPCV, SIMV+PSV, AdPSV
	Yes; Range: 10-1,600 mL	Yes; Range: 20-1,500	Yes; Range: 50-1,200	Yes; Range: 20-1,500			
	Yes; Range: Not specified	Yes; Range: 0-30	Yes; Range: Not specified	Yes; Range: 0-30	Yes; Range: 0.3-25	Yes; Range: 0.5-60	Yes; Range: 0.3-25
	4-80	4-80	4-80	4-80	02-99bpm	06-99bpm	02-99bpm
	Automatic	Automatic, decelerating	Automatic	Automatic, decelerating	0-100, variable	0-100	0-100, variable
	1:1, 1:1.5, 1:2, 1:3, 1:4, 1:5, 1:6, 2:1, 3:1, 4:1	1:1, 1:1.5, 1:2, 1:3, 1:4, 1:5, 1:6, 2:1, 3:1, 4:1	1:1, 1:1.5, 1:2, 1:3, 1:4, 1:5, 1:6, 2:1, 3:1, 4:1	1:1, 1:1.5, 1:2, 1:3, 1:4, 1:5, 1:6, 2:1, 3:1, 4:1	2:1 to 1:5	Not specified	2:1 to 1:5
	0-50%	0-50%	0-50%	0-50%	Off, 10-50%(increments of 10)	NA	Off, 10-50%(increments of 10)
	0-20 cm H2O adjustable, electronic PEEP	7-99 mbar, adjustable	7-99 mbar, adjustable	7-99 mbar, adjustable	10-70, 10-50 pediatric, adjustable	20-80, adjustable	10-70, 10-50 pediatric, adjustable
	Off, 4-20	0-20 cm H2O adjustable, electronic PEEP	0-20 cm H2O adjustable, electronic PEEP	0-20 cm H2O adjustable, electronic PEEP	0-20 electronic variable PEEP	0-20 variable	0-20 electronic variable PEEP
	Auto self-test, full test/maintenance programs	Adult and pediatric modes, standby in both modes, spirometry MV/TV selection	Adult and pediatric modes, standby, MV/TV selection	Adult and pediatric modes, standby in both modes, spirometry MV/TV selection			
	Leaks, resistance, compliance	Leaks, resistance, compliance	Leaks, resistance, compliance	Leaks, resistance, compliance	Self-verification and leak test, dynamic compliance, compensation, fresh-gas flow compensation	Self-verification test	Self-verification and leak test, dynamic compliance, compensation, fresh-gas flow compensation
	Yes	Yes	Yes	Yes	Peak and mean	Peak and mean	Peak and mean
	7-99 cm H2O	7-99 cm H2O	7-99 cm H2O	7-99 cm H2O	70 to -4 cm H2O	10-70 cm H2O	70 to -4 cm H2O
	Not specified	Not specified	Not specified	Not specified	-10 cm H2O, fixed, internal	Not specified	-10 cm H2O, fixed, internal
	Yes	Yes	Yes	Yes	PEEP referenced	PEEP referenced	PEEP referenced
	Yes	Yes	Yes	Yes	4-50cmH2O	5-60 cm	4-50cmH2O
	Not specified	Not specified	Not specified	Not specified	adjustable apnea alarm	Not specified	adjustable apnea alarm
	Yes	Yes	Yes	Yes	MV and TV	Not specified	MV and TV
	Yes	Yes	Yes	Yes	Yes	Not specified	Yes
	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Yes	Yes	Yes	Yes	Not required	Not specified	Not required
	Yes	Yes	Yes	Yes	Yes	Not specified	Yes
	Yes	Yes	Yes	Yes	Yes	Not specified	Yes
	Leakage, obstructions	Leakage, obstructions	Leakage, obstructions	Leakage, obstructions	High expired volume alarm	Not specified	High expired volume alarm
	Yes	Yes	Yes	Yes	Adjustable alarms	Adjustable	Adjustable alarms
	Optional	Optional	Optional	Optional	<30 secs	<30 secs	<30 secs
	Optional	Optional	Optional	Optional	Optional	Not specified	Optional
	Yes	Yes	Yes	Yes	Optional	Not specified	Adjustable
	Optional	Yes	Optional	Yes	Optional	Not specified	Optional
	Optional	Optional	Optional	Optional	Optional; Not specified	Not specified	Optional; Not specified
	Optional	Optional	Optional	Optional	Optional	Not specified	Optional
	Optional	Optional	Optional	Optional	Optional	Not specified	Optional
	Optional	Optional	Optional	Optional	Optional	Not specified	Optional
	Optional	Optional	Optional	Optional	Optional	Not specified	Optional
	Optional	Optional	Optional	Optional	Optional	Not specified	Optional
	Optional	Optional	Optional	Optional	Optional	Not specified	Optional
	Optional	Optional	Optional	Optional	None specified	None specified	None specified
	Yes:1; QVGA	Yes:1; Color 10" TFT touchscreen	Yes:1; EL	Yes:1; Color 10" TFT touchscreen	Optional: Up to 2; Not Specified	Not specified	Optional: Up to 2; Not Specified
	Yes	Yes	Yes	Yes	Yes	Yes	Yes
	Lead acid	Lead acid	Lead acid	Lead acid	Internal	AA	Internal, sealed lead acid
	2	1	4	1	Minimum 30 min, typical operating time 60min+	Not specified	Minimum 30 min, typical operating time 60min+
	Anti-voltrauma and anti-barotrauma software included.	Touchscreen ventilator control.	MRI compatibility up to 1,000-gauss line. 1.5 and 3T magnets	Auxiliary O2 option; front-loading drawer options; worksurface and flowblock illumination; motion-activated vaporizer lighting; choice of canister sizes; touchscreen ventilator control or touch and trak; auxiliary common gas outlet option.			
					Supplier Footnotes : <1>Formerly Blease.	Supplier Footnotes : <1>Formerly Blease.	Supplier Footnotes : <1>Formerly Blease.

EXPERIENCE FROM THE 2009 INFLUENZA OUTBREAK IN MEXICO: ONE YEAR LATER



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On April 23rd 2009, a news release informed the world about an influenza outbreak in Mexico due to a new virus (Swine origin AH1N1), with a high mortality rate among young people due to severe pneumonia. A few months later the influenza AH1N1 infection had spread rapidly from one country to another reaching the level of a pandemic, the first one in the 21st century.

Influenza AH1N1 in the ICU

Despite the small proportion of patients with pneumonia compared with the population infected and/or with mild symptoms (Perez Padilla 2009), there was suddenly an over-demand for admission of patients into hospitals and, specifically, into intensive care units (ICUs). It was evident that in Mexico this small proportion was already large enough to break down the ICU system. Official numbers of the 2009 outbreak show 72,481 confirmed cases and 1,198 deaths directly related to influenza AH1N1. The age group most affected was 20 to 59 years (www.salud.gob.mx). This was unexpected according to the



Figure 1. Nurses in a suburban hospital during the second outbreak of Influenza AH1N1 in October 2009

natural age distribution of those affected by influenza A, i.e. normally during childhood and older age. During 2009 in Mexico, we observed two important outbreaks: one at the beginning of spring and the second during late summer/beginning of fall. The second was more severe than the first one.

There is no doubt that the outbreak of influenza AH1N1 had a significant impact on our perception of biological threats in the ICU. Besides the terrible loss of human lives and the economic consequences of the pandemic, a learning process has made our Intensive Care System stronger. After the first wave of the pandemic from March to May 2009, there was intense activity to promote prevention as well as a specific action plan to deal with a potential second wave. There was national awareness about the risk of a new hit of influenza AH1N1 during the winter; therefore, authorities at every level of the health system implemented ways to promote sanitary measures such as hand washing, protection after sneezing, and vaccination campaigns. Besides these actions, information about the pandemic via the media/telecommunication systems enabled people to receive information almost in real-time. Thousands of brochures giving information about the outbreak were distributed. Interestingly, the influenza outbreak promoted strong multinational collaboration and high-impact journals worldwide invited authors to report their experience.

Life changed in Mexico, as did the way of treating community-acquired pneumonia at the ICU. The challenge was to control our procedures in preparation for a biological crisis in the ICU through an effective action plan.

Improvement of Equipment

A large investment was made in equipment to protect healthcare workers. There was a national vaccination campaign for immunisation against influenza (either A or AH1N1), equipment and personal protection (e.g. glasses, N95 masks, gowns, and gloves) (Fig. 1). Also, a large investment was made in mechanical ventilators to cover the expected demand, as well as acquisition of equipment for treatment of acute respiratory failure (ARDS), such as High Frequency Oscillatory Ventilators (HFOV) and Extracorporeal Membrane Oxygenators (ECMO).

A group of experts guided by the Federal Health Secretary (Secretaria de Salud) formed a task force to write “Guidelines for Influenza AH1N1” and “Guidelines for Influenza AH1N1 in Pregnant Women” (www.salud.gob.mx) to standardise the diagnosis, admission and treatment at the ICU of infected patients. The guidelines were widely distributed directly to public and private hospitals, as well as via the Internet.

According to epidemiological reports in Mexico (Perez Padilla et al. 2009; Dominguez Cherit et al. 2009), during the spring outbreak of influenza AH1N1, ARDS was highly aggressive and mortality in the ICU was around 40 percent, with high needs of airway pressures and FiO₂. Problems arose to adequately ventilate patients with severe pneumonia, the conventional techniques and the ARDS network protocol rapidly failed to keep patients with adequate modes of lung protection. There were many “trials and errors” to improve gas exchange and many explored rescue therapies for ARDS, like prone position, lung recruitment maneuvers, nitric oxide, HFOV and (in some cases) the use of ECMO (Fig. 2). Most intensivists used steroids and others used a combination of steroids and recombinant human activated Protein C as medical treatment for ARDS (personal communication, Dr. Asiscló Villagómez, Hospital 1o. de Octubre del ISSSTE, Mexico City).

Educational Meetings

There were a number of educational meetings held nationwide for influenza AH1N1. Symposia, forums, expert meetings, video-conferences, mechanical ventilation workshops, ventilator triage, and other various platforms and topics were presented at the main Mexican associations, academies and congresses during this crucial initial period.

Communications about our experience helped other ICU teams worldwide to prepare their own action plan and to generate useful databases to better understand the pandemic. Then, we received feedback to help face our second hit in summer/fall. Research and publications during the first pandemic of the 21st century was a very interesting issue. The influenza virus spread rapidly throughout the world, and research on the AH1N1 virus was produced worldwide. There are more than 13,000 citations on Google and more than 6,000 in PubMed where basic, experimental, epidemi-

ological, and clinical research are reported. Mexican authors reported three main epidemiological studies (Perez Padilla et al. 2009, Dominguez Cherit et al. 2009; Echavarría et al. 2009) two of them related to critically ill patients.



Figure 2. Patient with primary acute respiratory failure secondary to severe pneumonia due to Influenza AH1N1 treated with extracorporeal membrane oxygenation and high frequency oscillatory ventilation. Second outbreak of influenza in Mexico, October 2009

As expected, the magnitude of the second hit of the outbreak of influenza AH1N1 was harder than the spring outbreak. The ICUs were occupied with infected patients and specific areas of hospitals were isolated to receive patients with moderate symptoms. A novel strategy to cover more hospitals with specialised physicians was launched. The programme of Telepresence, using robots directed by remote control via wireless internet, was used for the first time in a biological crisis. This novel programme assisted three suburban hospitals in the State of Mexico, acute care facilities including emergency room, ICUs, and isolated areas for influenza. The programme showed that is feasible to provide assistance from highly specialised physicians to distant communities during an outbreak of influenza (Vázquez de Anda 2010).

Conclusion

One year after the experience of our first biological epidemic, we feel that Mexico is closing the cycle. The swine flu pandemic was less aggressive than expected; the number of persons that died is relatively low compared with the much higher number of infected people. Perhaps such unexpected low mortality was due to a good response to the challenge of a pandemic. The use of telecommunications, news, research, knowledge of epidemics, biotechnology and better equipment in ICUs, antibiotics, antiviral, vaccines, mechanical ventilators, and the importance of being prepared for disaster, might have been the strongest contributors to such a low mortality rate. Perhaps, we are changing/improving our fate. ■

DRUG ELUTING STENTS BALANCING RISK AND BENEFITS



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With the introduction of DES technology, a reduction in coronary restenosis rates was supposed to improve the incidence of myocardial infarction and mortality at least in more complex patient populations, such as those with long lesions, multiple vessel disease, diabetics, etc. However, after over seven years of systematic use in countries across the world, the angiographic and clinical improvements of restenosis have not translated into a reduction in myocardial infarction and death. Also, some adverse side-effects were associated with first generation DES, e.g. inflammation, delayed healing with poor re-endothelisation, late stent mal apposition, and endothelial dysfunction, described as “collateral side-effects” in preclinical and clinical studies with this early technology. Durable polymers and the drug itself have been associated with the above unfavourable effects. Furthermore, besides their initial advantages in the reduction of TVR and TLR over BMS therapy, we don’t know how these rewards would be maintained at long-term follow-up.

Long-term Outcomes in First DES Designs

As a result I would like to review some recent experiences with the long-term outcome of these first DES designs, which raised concerns about the safety/efficacy of these devices. In the pooled data from SIRIUS trials with the first Cordis/Johnson & Johnson sirolimus eluting stents (SES), at five years follow up, a significant reduction of TLR compared to BMS was reported, but they also showed a significant increase in overall and cardiac mortality over the entire follow-up period in the subgroup of patients with diabetes, a well-known difficult patient subset to be treated with PCI.

The concerns increase even further, when the higher mortality and Q myocardial infarction was observed beyond the first year, suggesting a specific device effect in these findings. In our ERACI III Registry, we compared first generation SES (Cypher, Cordis/J&J) and paclitaxel eluting stents (Taxus, Boston Scientific) with BMS and CABG in patients with multivessel coronary artery disease, and at five years of follow-up, there was a complete loss of the 1 year initial DES advantage over either BMS or CABG groups. Furthermore, there was a concern with the sig-

nificantly greater incidence of noncardiac death and myocardial infarction in the DES group after the first year of follow up compared with the other two groups.

The diabetic subgroup was at higher risk for hard cardiac events. Therefore, according to these long-term results, first DES generation do not have any protective effects in this traditionally complex cohort of patients to PCI procedures. A clear pathologic explanation is as yet unknown. However, diabetic patients have lesions, which are more lipid-rich, softer, with more endothelial dysfunction and prone to plaque rupture than the non-diabetic population.

An Explanation for Questionable Safety/Efficacy?

All of the above can induce progression of atherosclerosis and may lead to an enhanced inflammatory and thrombotic reaction, which can potentially be more pronounced with coated drugs and polymers stents. All can lead to processes that could end in late/very late thrombosis, where diabetes was identified in several registries as an independent predictor of stent thrombosis. Additionally, the ARTS 2 registry compared old BMS with first SES generation, at five years of follow up. Although the TVR rate with SES was significantly lower compared to BMS, it was ineffective in comparison to the TVR rate reported by the CABG group. It also reported a higher incidence (9.4 percent) of stent thrombosis in the SES treated group. Though this finding had no impact on late mortality in the study, it was responsible for over a third of Major Adverse Cardiac Events (MACE) rate in that trial.

TAXUS Confirms Loss of Initial Advantages

The TAXUS VI study also reported a complete loss of their initial advantage to BMS in patients treated with complex and long lesion subsets. All these long-term data raised concerns about the results of ongoing randomised trials comparing first DES generation versus CABG in the above cohort of patients with diabetes or complex multiple vessel disease. If we are going to achieve long-term negative results in trials such as SYNTAX,

AUTHOR GUIDELINES

ICU
MANAGEMENT



Content

Articles may focus on any management or practice issue in intensive care related to economics, quality of care or patient outcome. We only accept scientific papers with a clear connection to management and practise issues. We also invite opinions for publication in our Viewpoints section, which can be personal opinions of the author and/or reactions to articles published in prior issues. These are published at the discretion of the editors. Submissions may not have been published previously or be currently submitted for publication elsewhere. Articles must be written by independent authorities and any sponsors for research must be named. If manufacturers are named in an article, the text must present an unbiased view, not in support of any particular company.

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Length

- Articles: maximum 1400 words (less if figures or tables are included)
- Viewpoints: maximum 700 words
- News/research/product updates: maximum 200 words

Please note that contributions longer than the specified number of words may not be accepted.

Structure

Article texts must contain:

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- Names of authors with abbreviations for the highest academic degree
- Affiliation: Department and institution, city and country
- Main authors are requested to supply a portrait photo (see specifications below)
- Summary of one or two sentences (no more than 30 words) describing the content
- Contact name for correspondence and an email address which may be published with the article
- Website, if appropriate
- Acknowledgements of any connections with a company or financial sponsor
- Introduction, main text and summary/conclusion, with subheadings as appropriate
- Authors are encouraged to include checklists and/or guidelines, which summarise findings or recommendations
- References or sources, if appropriate, as specified below

Writing Style

Articles must be written in UK/British English (e.g. organisation, not organization), with short sentences, a clear structure (see above) and no bias. Full stops in numbers may only be used to indicate a decimal place; otherwise use commas as separators.

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Example of within text citation: [Edwards 2004; Edwards and Miller 2002; Miller et al. 2003].

Reference lists should be alphabetised by lead author and included at the conclusion of the submission.

Example of standard journal reference: Sydow Campbell, K. (1999) "Collecting information; qualitative research methods for solving workplace problems", Technical communication, 46 (4) 532-544.

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Acceptance

It is always at the discretion of our editorial board to accept or refuse submissions. We will respond to submissions within 8 weeks of receipt. We reserve the right to revise the article or request the author to edit the contents, and to publish all texts in any EMC Consulting Group journal, on the Internet and to list them in online literature databases.

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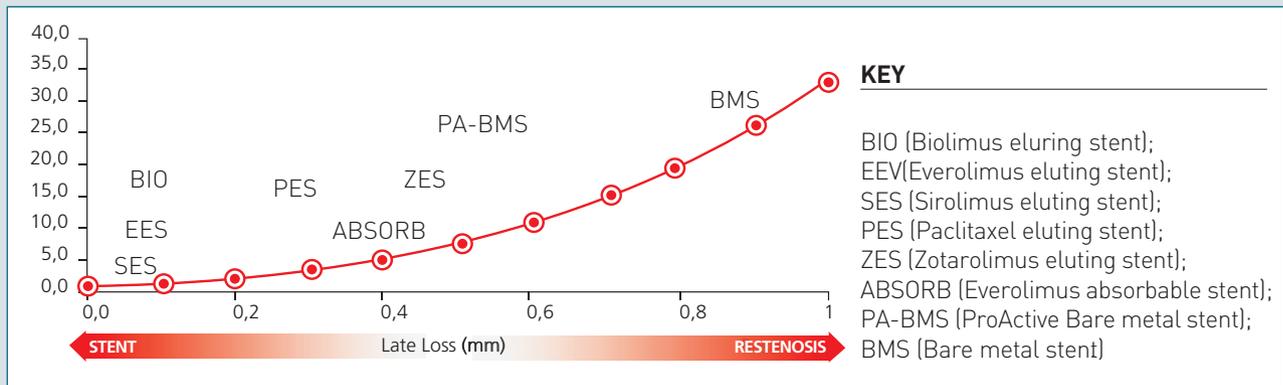


Figure 1. Balancing risk between safety and efficacy in stent era

FREEDOM, CARDIA etc, we should ask if these harmful results would be linked to an inadequate patient selection, since PCI practitioners are treating patients/lesions beyond boundaries or because we are comparing a well established revascularisation technique such CABG versus an almost obsolete first DES generation in which safety advantages over old BMS technology is controversial. Besides that, there are new randomised trials with the latest DES generation that are showing significant improvement in safety/efficacy.

During these years, we also understood the complex process to build the ideal DES design, where a combination of safety and efficacy should be the main goal of any DES technology. Moreover, we clearly recognised that minimal luminal diameter loss at follow up should be reduced to improve late outcome, although degree of such reduction is contentious and debatable. Some of the side effects with the first DES designs were related to durable polymers, essential in the first DES generation for a controlled release of the immunosuppressive agent. New technologies are coming with biocompatible polymers, biodegradable polymers or complete biodegradable DES design, all of them trying to avoid or minimise the undesirable side effects linked to durable polymers. Therefore, we now have positive randomised clinical trials with newer DES versus older generation head-to-head comparison. This means that the industry is working hard to solve many of these problems.

Other Limitations

Other limitations for the widespread use of DES are the requirements for long-term dual antiplatelet therapy, which was one of the major restrictions for first DES technology. There are subgroups of patients with limited compliance to that therapy, such as older age, upper and lower digestive tract bleeding, non responsiveness to clopidogrel, patients under oral anticoagulation therapy or unable to take dual antiplatelet therapy either at short or long term for concomitant non cardiac illness; all these clinical conditions, 30 percent of current PCI candidates, should be considered contraindications or restrictions for DES deployment. Hence, DES with biodegradable polymers, dedicated antithrom-

botic BMS designs with antithrombotic coating layers and paclitaxel coating balloon catheters are potential solutions for the above clinical circumstances. In addition to all these technology improvements, we also have new tools beyond DES, to reduce or prevent coronary restenosis.

Oral Therapies More Cost-Effective?

During the last decade, results from randomised clinical trials using systemic oral therapies after BMS implantation systematically reported positive results using either oral sirolimus, oral prednisone, oral thiazolidinediones or oral cilostazol. One of these trials also found a cost saving advantage of this therapy over DES. Perhaps these later groups of drugs in conjunction with the new DES designs should be tested in future trials searching frontiers in the most complex subsets of patients with coronary heart disease. Improving survival in the diabetic population should be the main research goal for interventional procedures, and amulti-therapeutic instead of single approach appears to be the most reasonable option.

Conclusions

With the introduction of the first DES generations, the market for coronary stents is slated to exceed 7.2 billion dollars by 2012. Backed by a greater number of PCI procedures and penetration, the U.S. represents the largest market for coronary stents worldwide. Collectively, the U.S, Europe and Japan account for about 85 percent of the global coronary stent market. The DES is forecast to reach a value of 5.7 billion dollars in 2012. However, many physicians, federal health agencies and insurance companies have a greater focus on long-term safety and closer assessment of late-stent thrombosis after DES implantation. New DES designs introduce new groups of actors to the market, like DES with absorbable polymers and completely absorbable coated stents, although long term safety/efficacy is needed. Furthermore, current DES designs need mandatory dual antiplatelet therapy, opening other alternatives with medical or interventional therapies during PCI, either alone or in combination with the latest generation of DES. ■

Country Focus: Germany

OVERVIEW OF THE GERMAN HEALTHCARE SYSTEM

The Federal Minister of Health, Philipp Rösler (Free Democrats), is a doctor. This is a good precondition for understanding the complexities of the healthcare system and for appropriate decision making. It is, however, not only the federal minister who influences the development of the health system, but multiple interest groups and important demographic, medical and economic changes.

The German health system is divided into an insurance sector with public and private insurance funds, and a healthcare sector. The healthcare sector covers a range of services and departments, including ambulatory outpatient care (provided mainly by individual doctors at their offices), pharmaceutical care distributed by pharmacists, inpatient care in hospitals and rehabilitation clinics, and a nursing care sector (caring for the increasing elderly population).

It is the complex network of interest groups that form the connection between this structure and the political arena. The 2000 hospitals, for instance, are represented by the German Hospital Federation, Deutsche Krankenhausgesellschaft. These interest groups act as legitimate partners of the political and democratic process in opinion and decision-making.

Insurance Sector and the Central Health Fund

There are 82 million people living in Germany; 85 percent are insured by statutory insurance funds, 11 percent by private insurance funds, and four percent are supported by different institutions or pay out of pocket. In Germany 250 billion euro is spent each year on healthcare, 10 percent of the gross domestic product. In international comparison, Germany ranked third in healthcare spending compared to GDP, following France with 11 percent and USA with 16 percent. The United Kingdom ranked fourteenth with eight percent.

Since January 2009, a central health fund collects and distributes the money for statutory in-

sured people, in total 50 million members and 20 million relatives. The fund gets its financial volume of about 174 billion euro (2010) largely from member payments. Currently, the employer of a member pays seven percent of the gross income of his employees. The employee pays 7.9 percent. Before 2009 insurance rates differed according to the fund, but today all rates are standard. Since 2004, funding also comes from the federal budget, supplementing 12 billion euro per year, and an expected increase to 14 billion euro in 2012.

At an income level of 4,162.50 euro per month (2010) an employee can switch to a private insurance fund. If one chooses to use a private fund, only under certain conditions such as job loss can he or she return to be covered by a statutory fund. Relatives, partners and children need an additional private insurance. If employees exceed this level they are under no obligation to leave the statutory fund. Such members pay 14.9 percent, including the employers' fee only up to 3,750 euro per month (2010). Relatives, partners and children, are insured for free.

There were 170 insurance funds in Germany at the end of 2009. Their income from member payments goes directly to the central fund to be redistributed to the insurance funds according to specific morbidity criteria. These compensational payments reflect the population that each fund serves. Some funds for instance have a higher portion of elderly people or of people with expensive diseases. The evaluation and distribution procedure works on a daily basis with administrative expenses exceeding 10 billion euro per year.



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Statistics:

Total population:
82,641,000

Gross national income per capita (PPP international \$): 32,680

Life expectancy at birth m/f (years):
77/82

Healthy life expectancy at birth m/f (years, 2003): 70/74

Probability of dying under five (per 1 000 live births): 5

Probability of dying under five (per 1 000 live births): 106/55

Total expenditure on health per capita (Intl \$, 2006): 3,328

Total expenditure on health as % of GDP (2006): 10.4

Figures are for 2006 unless indicated. Source: World Health Statistics 2008

Country Focus: Germany

Ambulatory Outpatient Care

Traditionally, doctors have provided ambulatory outpatient care from their offices. Legally defined, there are instances where specialised care can also be provided in hospitals, for instance ambulatory surgery, therapy for cancer patients and social paediatric therapy.

In Germany, the doctors associations contribute their income. They are public corporations and negotiate the overall budgets for their doctors in a defined region with the insurance funds. According to the medical services and other criteria, the corporations distribute the budget to individual doctors quarterly. Before the last health reform in 2008, the services were weighted by points, or appointments per doctor. The weakness in this system was a decline of euro per point when services and points increased while the global budget remained nearly constant. Now the doctors have defined fees in euro and it seems easier for them to calculate their income. If a patient visits a doctor, the doctor on the average gets 50 euro per quarter. If the patient has more visits, the fee, however remains constant. The physician can help himself only by controlling the number of visits. In the former system there was not such an incentive.

In 2008 the doctors had 7.5 cases per quarter per insured per year. In total, this is about 500 million ambulatory cases. Each case has 2.5 appointments on average per insured (total 1.2 billion appointments). The number of patient contacts with about 18 per insured per year is the highest in international comparison. It is nearly twice as high as in comparable OECD countries. People in Sweden for instance have about 3 appointments per insured per year (OECD data 2006).

GP Contracts

After the last health reform the insurance funds were obliged to offer their members a General Practitioner (GP) contract. The GP should act as a gatekeeper as it is the case in many other European health systems. The members are free to subscribe to this offer, but give up their free choice of doctors and hospitals. In return they get financial advantages, such as no doctors'

office fee. The negotiation of the contracts led to great differences within the doctors' corporations. The GP-Group is attempting to establish a main GP corporation for withdraws, but the development is not settled yet.

About 135,000 physicians work in the ambulatory sector; while 120,000 work in an office of their own, 40,000 as GPs and 80,000 as specialists. Additionally, about 10,000 doctors, mainly chief physicians at hospitals, have the right to provide services in a small and specific range of ambulatory services. In the last few years the number of Medical Care Centres (MCC) has increased dramatically. Ambulatory care evolved into stronger organisational structures. In total, about 6,000 doctors work in MCCs, with 500 out of 1,300 MCCs in the ownership of hospitals (2009).

Inpatient Care in Hospitals

The hospital sector is a powerful economic factor. One million people in 2,000 hospitals care for 17 million inpatient cases and 18 million outpatient cases. The turnover is close to 65 billion euro, nearly three percent of the GDP. Inpatient cases are remunerated by German Diagnosis Related Groups (G-DRG), a system which is adapted on a yearly basis. It comprises about 1,200 categories. The main idea is that money follows service. Before the introduction of the budget effect of the G-DRG in 2005, additional patients were cost factors for a hospital. The budget was negotiated annually with a calculated number of days plus a change rate, mostly below one percent. If a hospital had a plus in admissions – for instance about ten percent – it had to pay back about 75 percent of the additional income in next years' budget negotiations.

The costs of the additional treatments remained the responsibility of the hospital. These internal costs increased to a higher extent than the income of the hospital causing many efficient hospitals serious financial difficulties during that time period. With the budget effect of the G-DRG since 2005 the remaining pay of additional inpatient cases increases. Moreover, the hospital has the right to consent additional inpatient cases with the insurance funds – if there is a higher need for hospital care respectively. If the funds reject an agreement the hospital can go to the court. The remaining pay for

HOSPITALS AND REHABILITATION FACILITIES: 2008

	Number of facilities	Number of cases	Days of care	Length of stay (days)
Hospitals total	2,083	17,519,579	142,534,888	8.1
<i>General hospitals</i>	1,781	16,993,276	129,423,617	7.6
<i>Other hospitals</i>	302	526,303	13,111,271	24.9
Rehabilitation facilities	1,239	2,009,526	50,886,304	25.3
Total inpatient facilities	3,322	19,529,105	193,421,192	9.9

Source: Federal Medical Registry, Federal Statistical Office, 2009

contracted additional inpatient cases increases from 35 percent in 2005 to 100 percent in 2010.

Investment in Hospitals

Whereas the patient treatments are paid mainly by the insurance funds via G-DRG, further remunerating fees (95 percent of the hospital budget) are paid by the Bundesländer (five percent). This divided responsibility has been introduced 1972 and is called the dualistic financing system. The Bundesländer are responsible for the development, planning and investment financing of hospitals. Over many years, however, the investment rate has declined from 25 to five percent. This is due to shortages of public budgets and changing priorities. The idea of hospitals as institutions with over-capacity and over-utilization led to a political neglect of the hospital sector.

Currently, the DRG-Institute develops a comprehensive approach to hospital financing by integrating the investment com-

ponents into the DRG-system. At the end of 2010 the self-government – German Hospital Federation and the Federation of Insurance Funds – shall discuss proposals of the DRG-Institute in cooperation with the Bundesländer.

Looking Ahead

The political discussion about the hospital sector in the past mainly concentrated on the “cost factor”; hospital admissions, hospital beds and how to contain costs. In recent years however, the focus has changed. The political realm is quickly realising the future challenges within German healthcare due to changing demands of society. The need for highly qualified medical and nursing care will continue to increase, our society is aging as the portion of elderly people increases, and medical innovations shall accelerate. The amount of wealth and health production by the hospital sector shall become a decisive factor in the development of modern society. ■

NEUROINTENSIVE CARE UNITS IN GERMANY



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Neurocritical care is an evolving subspecialty of neurology, anaesthesia, intensive care medicine, and neurosurgery that is still in the process of development. Its focus is the care for patients with neurological and neurosurgical problems requiring intensive monitoring or special techniques. Over the past 10 years the field has evolved from a niche specialty limited to the largest tertiary care teaching hospitals into a distinct medical specialty that links neurology, neurosurgery, interventional neuroradiology, and critical care medicine in the comprehensive management of complex and life-threatening neurological problems in some parts of the world.

Development of Neurocritical Care in Germany

Neurological intensive care in Germany was born in the early fifties during the last polio epidemics. First independent neur-

ocritical care units (NICU) were established in the nineteen sixties in Giessen and Chemnitz. The German Neurological Society of Neurological Intensive Care and Emergency Medicine (DGNI) was founded on January 28 in 1984 (Kunze 2006).

The initiation of neurocritical care specialised units followed the German tradition. The historical growth and organisation of academic medical centres in Germany is quite different from many other countries. Many German university hospitals are built as separate buildings on a common campus or in different parts of town representing the notion of the different subspecialties to inhabit their own building. This concept includes the emergency services of which each department provides their own as opposed to one central emergency room and combined neuro-oriented critical care units.

Initially, the patients undergoing neurosurgical procedures were managed postoperatively in anaesthesia care units. Later the spectrum expanded to patients with traumatic brain injury, intracere-

Country Focus: Germany

bral and subarachnoid haemorrhage, and other conditions with increased intracranial pressure. Traditionally, these patients are managed under the care of anaesthesia and neurosurgery. In most hospitals, there are one or two anaesthesia-run critical care units for all postoperative including the neurosurgical patients.

Specialised units for management of patients with cerebrovascular diseases began to grow separately within neurology departments in the mid eighties, followed by combined or split stroke and neurocritical care units under the direction of neurologists with training in neurocritical care. This development enabled maturation of specialised therapies such as intravenous and intraarterial thrombolysis and haemicraniectomy, which are now standards of care. Most of these NICUs encompass 6-12 ventilated beds and an intermediate care section. First units were opened at the University of Hamburg, Giessen and Chemnitz, followed by other major centers such as University of Heidelberg (1986), Leipzig (1991), Munich Grosshadern, Hospital Frankfurt Nordwest, University of Wuerzburg, Charité University Medical Center, University of Dresden and Martin-Luther-University Halle-Wittenberg (1997). The German Society for Neurointensive Care and Emergency Medicine merged with the Section of Neurocritical Care of the German Society for Neurosurgery in 2009 to represent the units under the leadership of neurology and neurosurgery, whereas the German Interdisciplinary Union of Intensive and Emergency Medicine (DIVI), the German Society for Anaesthesia and Intensive Care Medicine (DGAI) support neurointensive care for neurological and neurosurgical patients in multidisciplinary units. Recently, all societies combined forces and efforts to unify and improve the care in this emerging field. The University of Heidelberg and Martin-Luther-University Halle-Wittenberg may serve as an example for excellent relationships between the neurology and neurosurgery services and with a tendency to work as a team and combine neurocritical care in one unit to heighten the level of expertise.

Model of a Neurological Neurointensive Care Unit

The spectrum of diseases treated in a neurological NICU cover cerebrovascular emergencies, status epilepticus, brain tumors, intoxications, hypoxic brain injury, traumatic brain injury, infectious, autoimmune, metabolic and neuromuscular disorders requiring intensive care as well as medical complications of neurological patients and disturbances of consciousness. Aside from cardiac and neurological state-of-the-art monitoring including:

- haemodynamics (PICCO and Flowtrac);
- end-tidal CO₂;
- continuous venous oxygen saturation (SvO₂);
- temperature, intracranial pressure (ICP);
- cerebral perfusion pressure (CPP);
- near infrared spectroscopy, continuous electroencephalography (EEG);
- somatosensory evoked potentials (SSEP);
- brain stem auditory evoked potentials (BAER);
- transcranial and carotid Doppler and Duplex;
- computed tomography (CT);

- magnetic resonance imaging (MRI) perfusion; and
- angiography studies, most NICUs have 24-hour access to diagnostic and interventional angiography in cooperation with neuroradiology services and to neurosurgical procedures, continuous renal replacement therapy and compassionate specialised care through certified neuro registered nurses with a staffing ratio of one nurse to two patients.

Expertise to perform transthoracic and transesophageal echocardiography, tracheostomies, multimodal monitoring including cerebral tissue partial oxygen pressure, jugular venous oxymetry, continuous cerebral blood flow, microdialysis, and brain temperature monitoring can be found in some NICUs. Specific therapies offered in the NICU include intravenous and intraarterial thrombolysis for acute ischaemic stroke, controlled surface and intravascular hypothermia and normothermia, decompressive haemicraniectomy, extraventricular drainage, craniotomy, burr holes, brain biopsy through the neurosurgical services.

In most places, neurology residents provide coverage for the NICU in 8-hour shifts during the week and 12-hour shifts during the weekend. Each resident spends half to one year in the NICU as part of their residency training with the opportunity to rotate through the operating room and other intensive care units for procedural training and experience in stabilisation of haemodynamics and renal replacement therapy. They are supervised by a board-certified neurologist or attending physician. All NICUs with neurology leadership are closed units.

The weekday starts with rounds at 7:00 am, which includes the sign-out from the night to the morning shift, hand over of the problem list and orders for each patient, and the neurological examination of all NICU patients. The vital signs, laboratory values, and medication list of every patient are reviewed and the NICU patients examined by a resident once per shift. Neuroimaging from the past 24 hours is reviewed with a neuroradiologist, decisions regarding interventions and difficult cases are discussed. The day team is responsible for arrangement of routine imaging, consultations, and performance of bedside procedures, transport of patients to routine imaging (CT, MRI, angiography) and procedures. The night shift is in charge of completion of documentation including discharge summaries, stroke registries, records of time patients spent on the ventilator, DRG coding, and ICU scores. The ventilators are managed by the resident and the nursing staff. The physiotherapy and speech therapy teams visit every patient six days of the week for active and passive training. Important teaching points from the intensive care point of view are from an organ-system-based approach and focus on outcome, code status, discharge planning, and more intense participation of the nursing staff, determination of diagnostic and therapeutic goals for each patient.

As most units were created and are run from the perspective of a neurologist who is interested in, but not formally trained in critical care, these patient related issues are often not part of the daily routine and thought process. A more detailed formal core curriculum and examination for subspecialty training in neurocritical care like the one that exists in the US, an initiative of the Neurocritical Care Society needs to be created.



Figure 1. Tobias J. Mueller, MD, PhD (right) and Katja E. Wartenberg, MD, PhD performing a percutaneous tracheostomy, NICU Martin-Luther University Halle-Wittenberg

The Role of Neurocritical Care Units Today and Tomorrow

Closed ICUs and the around-the-clock availability of intensivists are important because this model has been shown to reduce costs and improve outcomes. High intensity staffing (mandatory consultation of an intensivist or closed ICU) was associated with reduced mortality and length of stay (Pronovost 2002). Introduction of a neurocritical care team including coordination of care by a full-time neurointensivist, as well as inter-hospital transfer systems, the implementation of best-medical practices, and continuous staff education lead to a reduction of in-hospital mortality and length of stay without any change in readmission rates and long term mortality, decreased total cost, increase in proportion of patients who were discharged home (Suarez 2004; Mirski 2001; Diringer 2001; Varelas 2006). Neurointensivists recognise details in the neurological status, provide expertise in interactions of the brain with other organ systems, cerebral physiology, common metabolic derangements, prognostication of severe brain injury, end of life support and related legal and ethical issues. Additionally, neurointensivists offer competence in organ donation and multimodality monitoring and are interested in aggressive approaches (“time is brain”) as well as innovative management strategies (Rincon 2007). Therefore, we need to improve structure, effectiveness, and quality of neurointensive care, expand the multidisciplinary, combined neuroscience team approach

towards integration, centralisation, and education with a national and international focus on teamwork and research platforms. These are the aims of the Neurocritical Care Society (www.neurocriticalcare.org). Networking of specialists, national societies, developing a core curriculum for neurocritical care fellowships and management guidelines, planning and conducting multicentre trials are big steps towards these goals. ■

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ACTING OUTSIDE THE BOX: TEAM CARE BEYOND CLOSED INTENSIVE CARE UNITS TO IMPROVE SAFETY AND QUALITY



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The focus of our review is to describe the recent developments in the structure of the intensive care at the University Hospital Aachen (Universitätsklinikum Aachen = UKA). This process has been initialised in order to improve intensive care quality, safety and efficacy, which is an ethical, scientific, economical and social requirement for the next years. The changes in management and leadership have impacted the whole practice of intensive care resulting into measurable quality improvement. We will describe the structure including human resources, technology, organisational procedures and processes needed to achieve the goals of the strategic plan of the UKA. Beneficial effects of organisational changes in the interdisciplinary surgical intensive care unit (ICU) and interdisciplinary intermediate care unit (IMC) will be presented. The UKA is an university hospital providing medical and nursing care as well as research and teaching on highest level with about 220,000 in- and outpatients a year and about 5,500 employees and 2,700 medical students.

Evidence Supporting Closed Generalised Intensive Care Units

There is growing evidence supporting that dedicated ICU staff is beneficial. Several reviews have showed that high level of experience and intensive workload are producing a reduction in

the length of ICU stay and mortality (Pronovost et al. 2002; Young and Birkmeyer 2000). Many studies have demonstrated that closed ICUs staffed by trained, specialised intensivists are associated with a better outcome than open ICUs (Pronovost et al. 1999; Dimick et al. 2001). We define a closed ICU as a unit that has transferred all patients to an intensive care team who

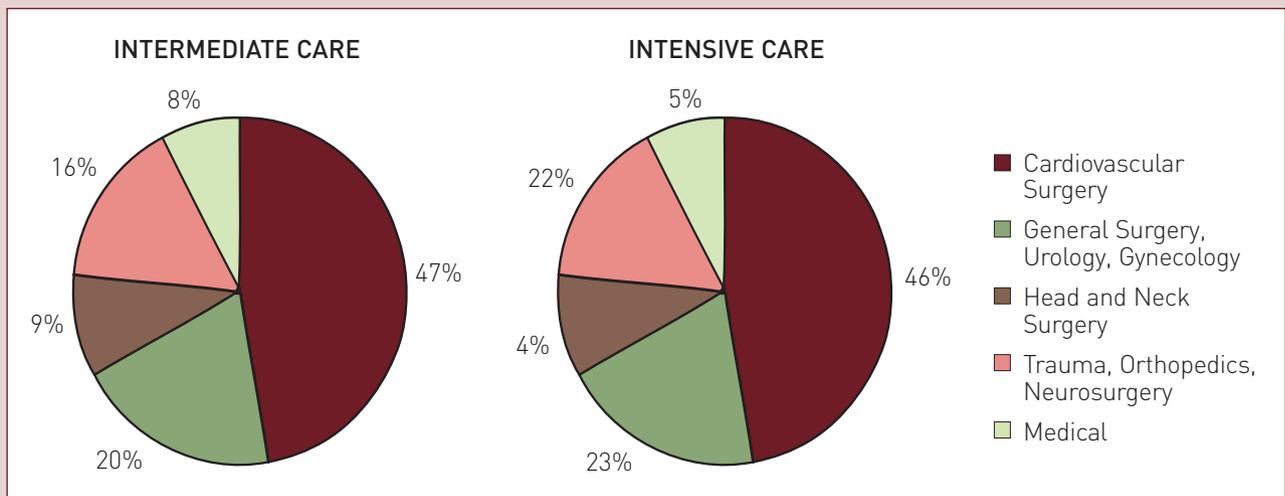


Figure 1. Allocation of patients on IMC and ICU to different surgical specialties

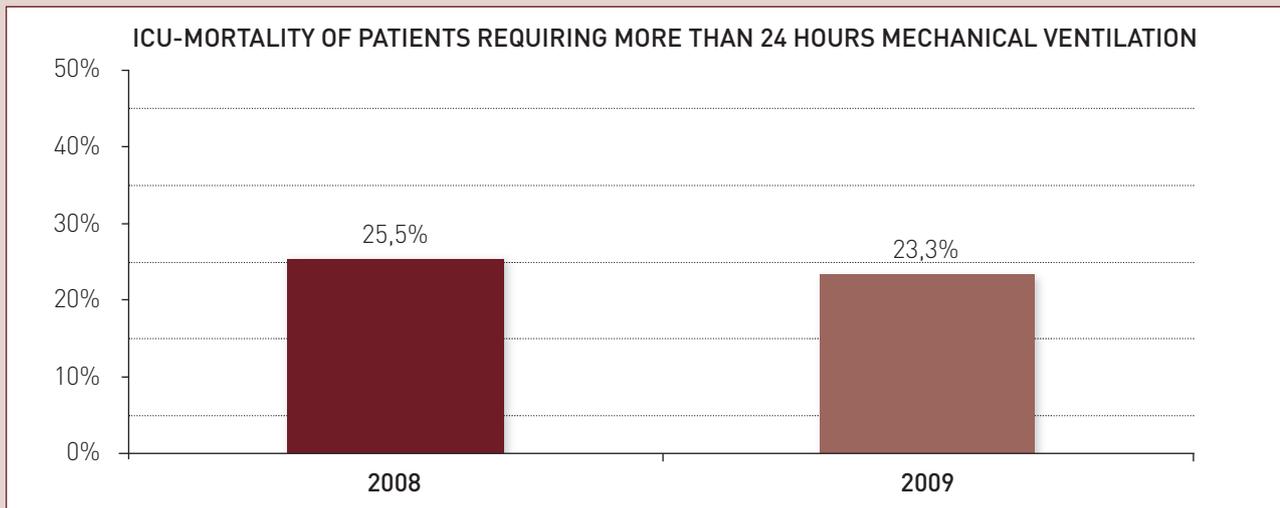


Figure 2. Mortality of patients with more than 24 hours of mechanical ventilation in the ICU 2008 and 2009.

directs their care – taking primary responsibility for the therapeutic plan and patients care. It is mandatory that the overall responsibility is shared with the primary surgical department for all patients admitted to the ICU.

Another important ICU-organisational aspect is whether delivery of critical care of specialised ICUs providing diagnosis-specific care for selected groups of critically ill patients is associated with clinical benefits. It was suggested that ICUs with greater diagnostic diversity are associated with worse outcome (Shortell et al. 1994). Recently, the association between specialty ICU care and the outcome of critical illness has been evaluated retrospectively analysing 84,182 patients admitted to 124 different ICUs in the US. It could be demonstrated that in this diverse large group of United States hospitals, risk-adjusted in-hospital mortality did not differ between specialised and non-specialised generalised ICUs (Lott et al. 2009). Furthermore there was no difference between specialised and generalised ICUs in the length of stay. Admission of patients to a non-ideal specialty ICU, as might occur if a hospital has a limited number of specialty ICUs, was associated with significantly higher adjusted mortality.

ICU Outside the Box

There are several ways of extending the availability of intensivists outside the ICU box. Due to the shortage of ICU beds in the UK, critical outreach teams have been established. These teams care for ICU patients post discharge, as well as critically ill patients on general wards and on high dependency units (HDU) in order to avoid unnecessary admissions to ICU. These HDUs, or step down units are an alternative answer. In Germany, these units are usually called intermediate care units. These units provide a lower staff-to-patient ratio as the level of critical illness is lower compared to an ICU patient. Sometimes these units are attached to ICUs, sometimes they are attached to the general wards aiming to care for patients with a required level of support between the high level care

area (ICU) and low level area (general ward). As this group of patients needs to be discharged frequently from an ICU to create a bed for an emergency case, the chance of deterioration is high when there is no safety net like an intermediate care unit available. In our institution, we have defined a set of criteria that create a basis to decide when a patient is ready for discharge from ICU to the intermediate care unit or vice versa (Figure 1).

ICU Concept in Aachen

The process of organisational changes at the UKA in Aachen began in 2005. Prior to that time, intensive care medicine was provided in several specialised ICUs. The medical and neurology ICUs have been kept as specialised ICUs, and a joint venture was initiated that included all specialised surgical and the anaesthetic ICU. The change resulted in a new ICU structure – the creation of a department of interdisciplinary intensive medicine “Operative Intensivmedizin” including all surgical and trauma ICU beds. We will discuss the development process of this department further later on in this review. The new department of interdisciplinary intensive medicine “Operative Intensivmedizin” is led and organised by an ICU leader and a dedicated ICU team including anaesthetists, surgeons and nurses. The ICU leader and consultant intensivists are board certified anaesthetists, who are additionally certified in the subspecialty of intensive care medicine. They have been scheduled during daytime hours to exclusively provide clinical care in the ICU. During nighttime hours, one ICU consultant has been on call at home, with ICU residents working exclusively in the ICU.

The main feature of this concept is the interdisciplinary, patient-focused, and respectful teamwork of many healthcare providers, but most importantly between intensivists and surgeons. Intensivists and surgeons perform daily joint rounds during which therapeutic decisions are made. Furthermore, the provision of postgraduate ICU-training for all anaesthetic and surgical trainees is essential and mandatory in ICU board certification.

In 2008, the board of directors of the UKA and the medical faculty decided to further the organisation of intensive care medicine in Aachen. They established the first chair of anaesthesiology with the focus on surgical intensive care medicine. Thus, there are now two chairs of anaesthesiology in place at the UKA. The two chairmen are deputies of each other. The two separate departments share the same strategies, including staff recruitment and development, research, under- and postgraduate teaching. The academic department of interdisciplinary intensive medicine “Operative Intensivmedizin” now includes the previous 42 beds and a 6 bed burn unit has been added, as well as a research team which runs its own basic-science laboratories.

The head of department and several consultants are present during daytime hours to exclusively provide clinical care on the ICU. In order to meet the challenge of the increasing morbidity of ICU patients, one consultant intensivist is now present exclusively on the ICU during the night shift. Thus, there is continuous high-level critical care provided 24 hours a day, 7 days a week. In addition, a continual supervision of trainees and residents is guaranteed. On average, there is one resident looking after ten ICU patients and the average nurse-to-patient ratio is 1:2.5. Strategies to improve quality and patient safety have also been enhanced. An increasing number of standard operating procedures and well-defined clinical pathways have been established to ease the application of evidence-based critical care treatment. Furthermore, clearly defined responsibilities, a matrix of regular meetings, national and international benchmarking, quality assessment audits and enhanced team-communication initiatives have been introduced.

Intermediate Care Concept in Aachen

In 2005, a new intermediate care concept was also established. The organisational structure at the UKA included an interdisci-

plinary separate Department of Intermediate Care (IMC). This structure was unique in Germany at the time. The IMC Department comprised up to 48 beds and was run by an IMC leader and a team including physicians, cardiologists, gastroenterologists, nephrologists, anaesthetists, surgeons and nurses. This team looked after all medical and surgical intermediate care patients.

In 2008, IMC divided into two separate entities: a medical unit and a surgical unit. The surgical IMC unit runs under the leadership of the head of department interdisciplinary intensive medicine “Operative Intensivmedizin” and the medical IMC unit runs under the leadership of the head of department of cardiology. Additionally structural and quality changes parallel to the department of intensive care were initiated.

Thus, the surgical unit of the department of interdisciplinary intermediate care is led and organised by an ICU leader and an IMC team including intensivists, anaesthetists, physicians, surgeons and nurses focused on the care of critically ill surgical patients. The IMC leader and consultant intensivists are board certified anaesthetists who additionally certified in the subspecialty of intensive care medicine and a consultant, who is a physician. Consultant coverage is guaranteed during daytime hours exclusively providing clinical care on the IMC. During nighttime hours, an ICU consultant is on call at home with an IMC resident being present exclusively on the IMC.

There is on average one resident looking after 12 IMC patients during the day and the average nurse-to-patient ratio is 1:4. There is one resident present exclusively on the IMC during the night shift, who is responsible for 24 patients and a consultant on call. Thus, continuity of high-level clinical care is once again provided over 24 hours, 7 days a week.

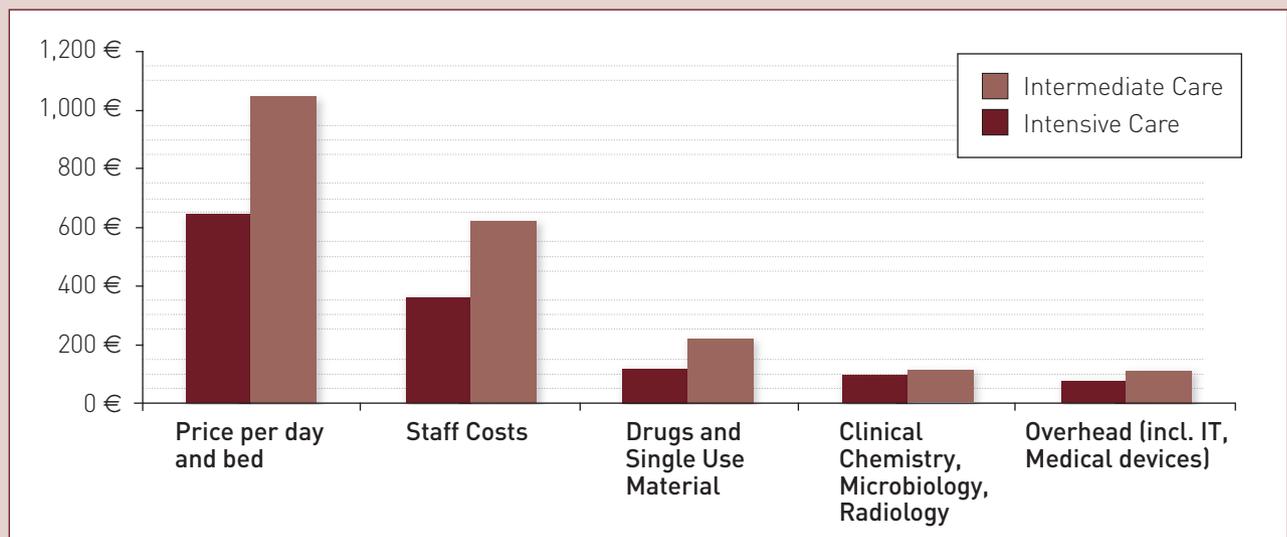


Figure 3. Total and partitioned costs of IMC and ICU Bed per day and patient in the University Hospital Aachen 2009

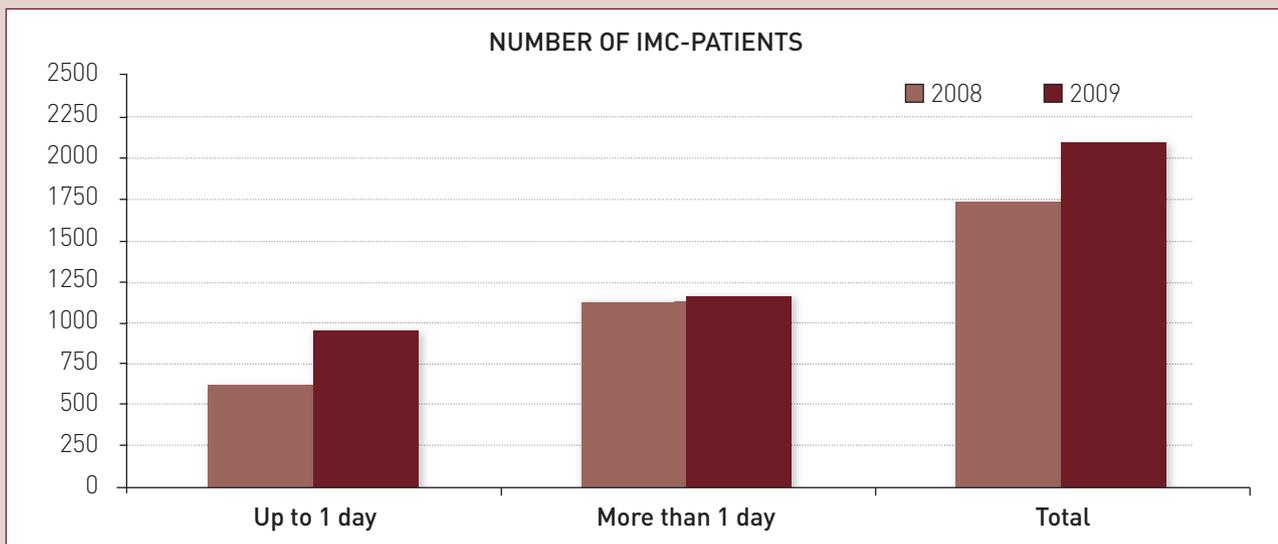


Figure 4. Number of IMC patients 2008 and 2009 with length of stay up to one day vs. more than one day and total patient number

Comparing Surgical ICU and IMC Data Before and After the Organisational Changes

In 2009, both the ICU and IMC departments treated more cardio-thoracic and vascular surgical patients than patients from all other surgical departments (Figure 1). We successfully allocated all surgical patients in our surgical ICU and IMC and could provide care for medical patients in addition (5-8% of the total number of patients).

Compared to 2008, we observed an increase in the severity of illness and morbidity in our group of ICU-patients. The case mix index on ICU increased on average by 8% from 5.97 to 6.46, in the group of more critically ill patients requiring more than 24hr ICU treatment, there was even an increase of the case mix index by 11%. Furthermore the number of patients requiring more than 24hrs of mechanical ventilation increased by 3%. This shift resulted in an increase of length of ICU stay from 4.9 to 5.4 days. Despite the substantial increase in the severity of illness in our ICU patients, we could reduce the mortality in the patients requiring more than 24 hrs of mechanical ventilation from 25.5% in 2008 to 23.3% in 2009 (Figure 2). This outcome improvement may be in part due to the organisational changes and several quality improvement initiatives.

The average cost of an ICU bed in 2009 was euro 1146 (Figure 3).

After reorganisation of the surgical IMC, more patients could be admitted to this unit. There was a total increase in the number of treated patients of 21% in 2009 compared to 2008 (Figure 7). Analysing the data there was an increase of 53% in the group of patients requiring IMC up to 24 hrs and of 3% in patients who needed the IMC more than 24 hrs (Figure 4). This large increase of treated patients was possible because we could reduce the length of stay by 18%. The reduction in the length of stay occurred despite an increase in the severity of illness in the IMC patients. The case mix index on IMC increased on average by 4%

from 5.2 to 5.5, in the group of patients requiring more than 24hrs of IMC treatment, there was an increase of the case mix index by 16% from 6.3 to 7.3. The associated mortality of IMC patients decreased from 1.6% in 2008 to 1.1% in 2009.

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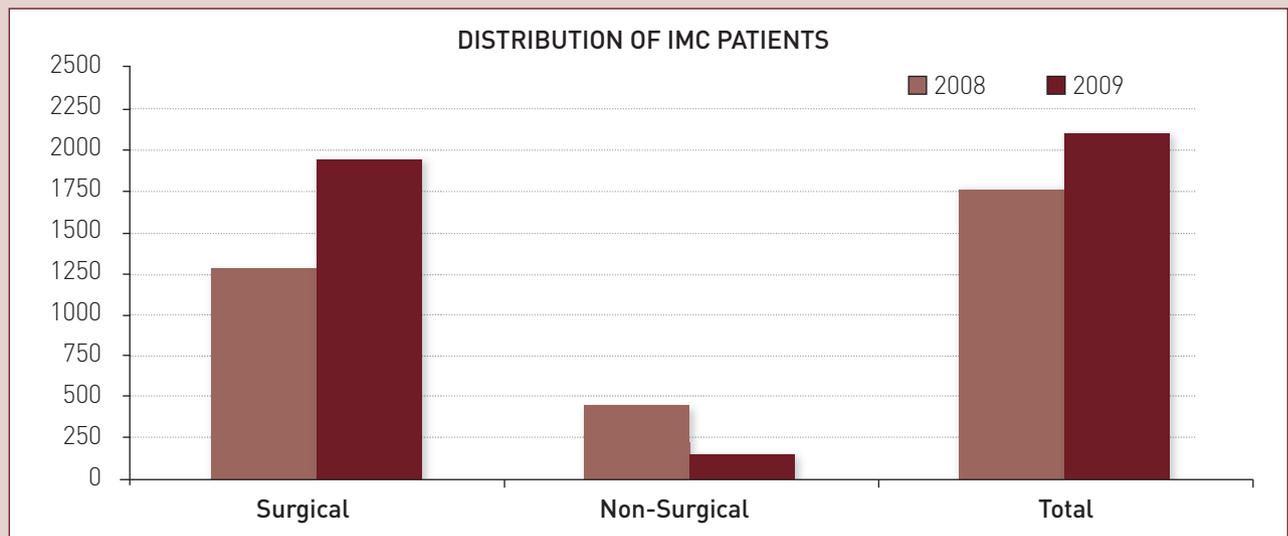


Figure 5. Surgical versus non-surgical patients on surgical IMC 2008 and 2009

The distribution of patients changed substantially after the organisational changes. There was an increase of surgical patients from 1273 patients in 2008 to 1926 patients in 2009 (+51%) associated with a decrease of medical patients from 462 in 2008 to 165 in 2009 (- 64%) (Figure 5).

Clearly the organisational changes enabled a substantial higher number of admissions, hence increasing the number of performed surgical procedures in the OR.

The total cost of an IMC bed/day was euro 637. Comparing the cost between ICU and IMC we could identify more staff, drugs and devices required on the ICU to maintain the higher level of care as an explanation of the higher cost (Figure 3).

Advantages of the Aachen Concept of Surgical Intensive Care Medicine and Intermediate Care

After examination of the positive results after the organisational changes of the interdisciplinary surgical ICU and interdisciplinary surgical intermediate care unit (especially between 2008 and 2009), there are several issues to be considered.

The structure is based on an effective leadership which has built a caring ICU team including more than 40 intensivists, and more than 140 nurses, physiotherapists and other staff, including a case manager who enables the timely transfer of patients to rehabilitation facilities. The size of the departments requires clear defined objectives, planning, organising, monitoring and communication to build and maintain a dedicated team, while also allowing for a wide flexibility to balance personalities, skills and talents. This team is able to provide a continuity of intensive care on an experienced consultant level, which is associated with better ICU-outcome. The established staffing model furthers the interdisciplinary ICU team approach to critically ill patients with improved timely patient evaluation and therapeutic decisions and additionally enhanced communica-

tion and collaboration with all surgical departments. In addition, it is important to respect the traditional structure between medical and surgical/trauma ICU patients.

The focus on improvement of quality, safety (e.g. same equipment at all ICU beds) and risk reduction has resulted in robust standardised care at the bedside combined with ICU expertise to add individualised care whenever required. In addition, an emphasis on teaching has improved postgraduate training, which is also important for the motivation of the trainees and beneficial for the patient. The early diagnosis of severe sepsis in IMC is a good example of the benefits of this improved level of care. We have observed several severe septic patients on IMC receiving early, standardised sepsis bundle treatment according to the Surviving Sepsis Campaign, thereby improving very rapidly and consequently avoiding ICU admission. The enhanced training and research activities have also proven to be an attraction for new members of staff.

Clear defined responsibilities and clinical pathways in IMC have resulted in improved processes, for example, the reliability of the OR-schedule or admission of an emergency patient. The improved process of ICU discharge and post ICU care is another important area. Due to the improved cooperation between ICU and IMC teams, delayed ICU discharges could be reduced. This is very important, as an increase of ICU length of stay is associated with increased risk of nosocomial infection, increased costs, lower efficiency of resources and the threat of ICU bed shortages (Zimmerman et al. 1996). On the other hand, early discharge of ICU patients will result in readmissions and increased risk of prolonged ICU stay and mortality. Thus, the improvement of interfacing issues between ICU, IMC, OR and general ward has been key in the success.

Future Directions and Challenges

In general, the major task of intensive care medicine is to improve the quality of care continuously, by preserving human life and providing suitable rehabilitation as soon the patient starts to recover.

In addition, it is essential to provide adequate palliative care and support for family and patients in the end of life situation.

At the University Hospital Aachen we have the vision to establish a centre of excellence for ICU within the heart of Europe. Therefore, we feel the integration of surgical intensive and intermediate care departments into one joint department is the next major step to improve quality, safety, flexibility and availability of ICU bed capacity for elective and emergency surgical patients. The development of the team and structure will be continued. Soon we will introduce psychological support for patients, relatives and staff including supervision for the team. A continuous benchmarking on regional, national, international is obligatory to ensure transparent quality assessment, safety and economical value. Finally, another major step towards our vision is the planned joint venture with the "Akademisch Ziekenhuis Maastricht" (AZM) in the Netherlands, in order to establish the first joint European University Hospital. ■

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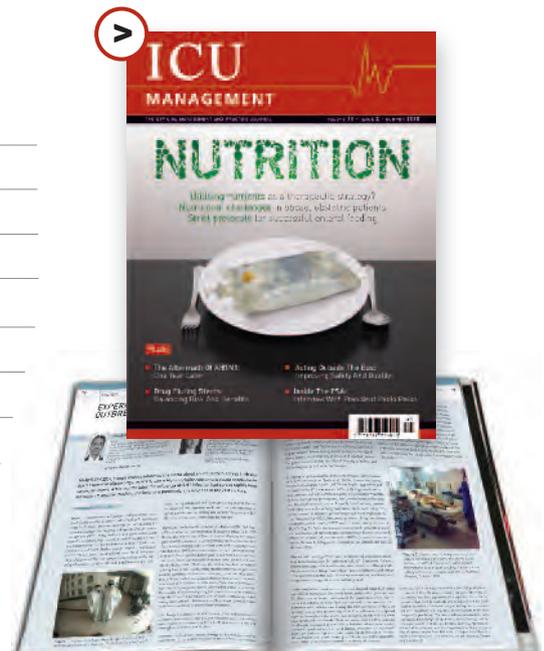
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ICU MANAGEMENT





INTERVIEW WITH PROFESSOR PAOLO PELOSI

Professor Paolo Pelosi is Associate Professor in Anaesthesiology at the University of Insubria, Varese, Italy. Born in 1963 in Milan (Italy), he graduated in Medicine and Surgery and specialised in Anaesthesia and Intensive Care at the University of Milan. He works both in clinical and research fields related to different areas of Anaesthesiology. And he is deeply involved in national and international educational training and teaching programmes in the field. Prof. Pelosi also a member of the advisory board of several international meetings and journals, and serves as an Editorial Board Member of ICU Management. Since January 2010, he has also very proudly served the European Society of Anaesthesiology (ESA), as President.

S.S. What is your greatest interest / area of expertise?

P.P. My main interests are: 1) Respiratory mechanics and morphological analysis of the lung by Computed Tomography scan during general anaesthesia and in acute respiratory failure; 2) Ventilatory management of patients during general anaesthesia and with acute respiratory failure; 3) Airway conditioning during mechanical ventilation; and 4) Non invasive ventilation.

S.S. What poses the greatest threat to patients in ICUs (infections, staff ratios, lack of equipment, medical errors)?

P.P. I personally believe that medical errors, staff ratios and infections are really serious problems not only in ICU but also outside the ICU. That is one of the reasons why during Euroanaesthesia 2010, the Helsinki Declaration on Patient Safety in Anaesthesiology will be signed. It focuses on how to reduce errors and enhance patient safety by the implementation of European policies, including infection control and staff organisation. This declaration emphasises the key role of Anaesthesiology in promoting safe perioperative care.

S.S. What role does the manager / head of an department play in improving outcomes and changing the hospital environment?

P.P. I feel that the head of an Anaesthesiology department may play a relevant role in the organisation of a system in which outcome can be improved. In this respect, the optimal clinical management of our patients is the best way to improve their outcome.

In my opinion, teamwork, and the creation of a team are essential. Work teams contribute most effectively to the final success to improve outcomes. Of course, building a team, and working as a team is not easy. However, belonging to a team, in the broadest sense, results of feeling part of something larger than yourself.

These are some tips on how to create a team:

Clear Expectations: Clear expectations must be defined and communicated in advance, demonstrating constancy of purpose in supporting the team with resources of people, time and money.

Context: Clearly identify the strategies to the accomplishment of defined goals

Commitment: All team members must be excited and challenged by the

team opportunity and feel that the team mission is important. Working in a team, each member must feel there is a chance to build individual as well as general skills.

Competence: It is essential that all members have the knowledge, skill and capability to address the issues for which the team was formed. If some help is needed, adequate support must be organised.

Charter: Individual area of responsibility, designed to accomplish the mission must be defined.

Consequences: From the initiation, rewards and recognition (and penalties) must be clearly set out.

Cultural Change: Everyone must recognise that the team-based, collaborative, empowering, enabling organisational culture of the future is differs dramatically from the traditional, hierarchical organisation currently in place. If we work well together, we will all share in the successes.

In addition to the creation of a team environment in the department, there are other important organisational staples that are instrumental in its success:

Guidelines: Guidelines are necessary to standardise the level of care in each unit. Independent from individual expertise, medical and non-medical staff must have clear rules to adhere to. The application of evidence-based medicine is essential in improving outcomes and reducing costs in our units. Of course, reality dictates that guidelines should be adaptable for each individual case / patient.

Education: Continuous education, within and outside the group, is essential to update and improve medical training of the personnel.

Research: Promoting new interests and the development of knowledge in each unit is crucial part of advancing the profession.

Innovation: Team members should be always open to new ideas, remaining

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critical but with a positive attitude. Putting the results of new ideas into practice takes time, but we mustn't allow good opportunities and innovations to pass us by. An open and constructive relationship with colleagues from other specialties is another important element in improving the quality of our treatment.

Non-Medical staff: There are a number of key team members who play relevant roles in anaesthesiology management. For this reason, constant updates and discussion are needed between medical and non-medical staff.

S.S. Has the current economic downturn affected healthcare across Europe? What do you think the future holds?

P.P. In general, the current economic crisis has not negatively affected healthcare. However, it has cast a spotlight on the need for careful management of economic resources in the future. More attention is needed on how much we spend in the daily treatment of our patients and organisation of anaesthesiology departments. For this reason, at Euroanaesthesia 2010, several sessions focus on quality improvement, quality markers, safety indicators, and cost efficiency, as well as the use of evidence-based medicine in every day in anaesthesiology practice. Additionally, the development of strong relations with industry, which is based on common strategies and objectives that are mutually beneficial, is essential to achieve ambitious targets.

S.S. Have you some wisdom to impart to those entering the field?

P.P. Anaesthesiology is a well-recognised medical specialty whose interest is a continuum of patient care involving pre-operative evaluation, intra-operative and postoperative care and the management of systems and personnel that support these activities. In this regard, the concept of peri-operative medicine integrated into anaesthesiology is of fundamental importance, within a multidisciplinary approach. In fact, anaesthesiology includes many different areas of expertise, such as anaesthesia, intensive care, emergency medicine and pain treatment. All these components together, and not independently, are fundamental to making anaesthesiology one of the most fascinating, continually developing and innovative areas in medicine in the forthcoming decades. Anaesthesiology requires daily sacrifice but may also serve to enhance and change your personal attitude with regards to human relationships and life in general.

On thing is assured, if you choose to work in the anaesthesiology field, you will never be the same... ■

IN FOCUS:

EUROANAESTHESIA 2010

S.S. Can you briefly describe the focus of the EUROANAESTHESIA 2010 congress?

P.P. Euroanaesthesia 2010 is the sixth annual meeting of the European Society of Anaesthesiology (ESA) is focused on Education, Research and Innovation.

The Scientific Programme Committee has planned a comprehensive programme including refresher courses, interactive discussions, workshops and abstract presentations. Internationally renowned clinical and scientific experts in the field of anaesthesiology have been invited together with lecturers from other related areas of expertise. This reflects the vision of the ESA to develop closer communication and cooperation with other scientific societies, which have expertise in specific medical areas with mutual interests.

As previously mentioned, during Euroanaesthesia 2010, the Helsinki Declaration on Patient Safety in Anaesthesiology will be signed. The European Board of Anaesthesiology (EBA) must be specifically thanked for its important role played in the organisation of this event. A specific session organised by the European Board of Anaesthesiology in conjunction with the ESA will focus on how to reduce errors and enhance patient safety by the implementation of European policies.

The one-day postgraduate interactive European Patient Safety Course, held by international experts, will provide also insights into how errors evolve in medicine, what the root causes

are and how patient safety can be improved.

Specific sessions will be dedicated to: a) "Hot topics" in anaesthesia, critical care medicine, emergency medicine and pain medicine; b) Changes in our profession: Intensive Care as part of the residency programme, and the increasing importance of women; c) The role of National Societies of Anaesthesiologists; and d) Quality assurance in the management of postoperative pain (organised by the World Federation of Societies of Anaesthesiologists).

S.S. How has your experience as ESA President been so far?

P.P. My experience as ESA President is exciting and very promising, so far. This is due to the fact that all members involved in the Society at any level are actively and positively contributing to reach all the goals we are aiming for. In order to be competitive and continuously updated, it is essential that anaesthesiologists are encouraged to keep learning and growing in their fields of expertise. This implies a momentous effort in the continuous education, research and innovation process that ESA actively supports in different forms. In particular, joint programming efforts can deliver results that individual countries cannot achieve in isolation. ESA should further encourage cooperation between European countries through cutting-edge infrastructure and joint policy-making for education, research and innovation. ■



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- 1-3 Sepsis 2010
Paris, France
www.sepsisconference.com
- 5-8 32nd Congress of Clinical Nutrition and Metabolism
Nice, France
www.espen.org
- 18-22 European Respiratory Society Congress
Barcelona, Spain
www.erscongress2010.org

OCTOBER 2010

- 7-8 IT @ Networking 2010
Brussels, Belgium
www.hitm.eu
- 10-13 23rd Annual Congress ESICM
Barcelona, Spain
www.esicm.org

NOVEMBER 2010

- 5-6 1st ESA Autumn Meeting 2010
Budapest, Hungary
www.euroanaesthesia.org
- 16-18 Doppler-Echocardiography in Intensive Care Medicine
Brussels, Belgium
www.intensive.org
- 30-2 16th Postgraduate Refresher Course
Brussels, Belgium
www.intensive.org

DECEMBER 2010

- 2-4 Resuscitation 2010
Porto, Portugal
www.congress.erc.edu
- 5-8 Respiratory Monitoring
Rome, Italy
www.intensive.org

JANUARY 2011

- 15-19 Society of Critical Care Medicine (SCCM) Annual Congress
San Diego, California, US
www.sccm.org

FEBRUARY 2011

- 25-26 16th International Symposium on Infections
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¹ Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med.* 2009; 360(14): 1418-1420.

² FDA 510(k) clearance.

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