

# ICU MANAGEMENT



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# Hypothermia in Care

ISSN = 1377-7564

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- WARMING/COOLING UNITS
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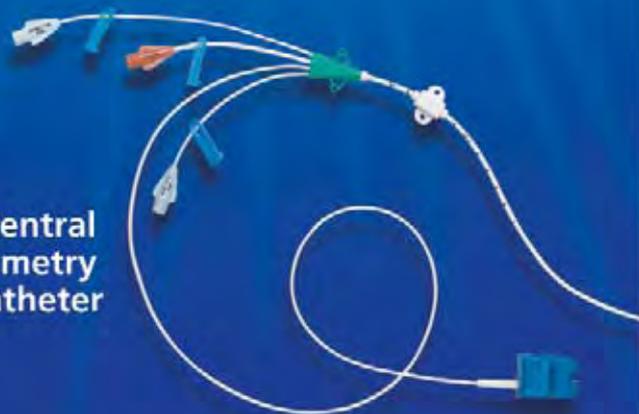
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## Hypothermia in Care

Medical professionals have long recognized the therapeutic benefits of regulating body temperature. In recent years, however, therapeutic hypothermia has garnered increased attention for its potential applications in treating several critical medical conditions. Indeed, this cool therapy has become a hot topic in the intensive care community.

Over the course of the past several years, medical professionals have conducted a number of cutting-edge studies regarding new induction methods and new applications of therapeutic hypothermia. New cooling methods have come onto the market, and more information is now available about the relative advantages and drawbacks of these methods. In addition, new applications of therapeutic hypothermia, encompassing a variety of medical conditions, are being explored. These studies have sparked renewed dialogues among critical care practitioners regarding the safety, effectiveness and practicality of induced hypothermia in treating a variety of conditions.

Despite the potential benefits of induced hypothermia for patients recovering from stroke, traumatic brain injury and cardiopulmonary resuscitation, amonremain wary of the negative side effects sometimes associated with therapeutic hypothermia. Thus, steps towards incorporating induced hypothermia into intensive care therapies are tempered by concerns that the risks of the procedure may not justify the benefits gained from its use.

This issue of *ICU Management* joins the dialogue on therapeutic hypothermia by highlighting some of the therapy's applications and exploring managerial aspects of its implementation. First, Professor Girbes discusses steps that the most effective ways for an ICU manager to introduce therapeutic hypothermia into the ICU. In particular, he focuses on change management techniques that may smooth the transition to this new practice. In addition, Dr. Nolan provides an overview of the application of therapeutic hypothermia following cardiac arrest, highlighting those factors that require particular attention when applying hypothermia in this case. These instructive articles increase our awareness and understanding of therapeutic hypothermia and enable us to make better-informed decisions regarding its implementation in our own critical care settings.

As new technologies continue to evolve and old procedures take on new forms and uses, *ICU Management* hopes contribute to dialogue in the critical care community by highlighting key technological developments and considerations for our readers. Induced hypothermia is no exception. We hope that you will find the articles in this issue a useful starting point to examine the possibilities for therapeutic hypothermia in your own facilities, weighing the practical medical and administrative ramifications of introducing this therapy into your specific clinical setting.

Letters to the Editor & Requests for References Cited in *ICU Management*  
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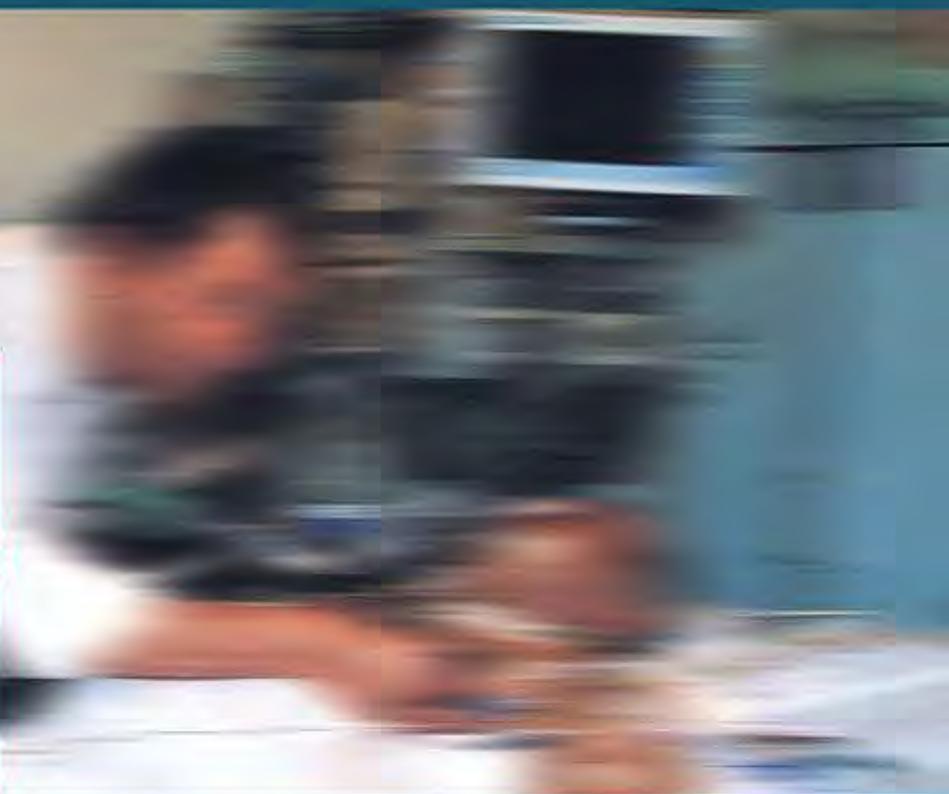
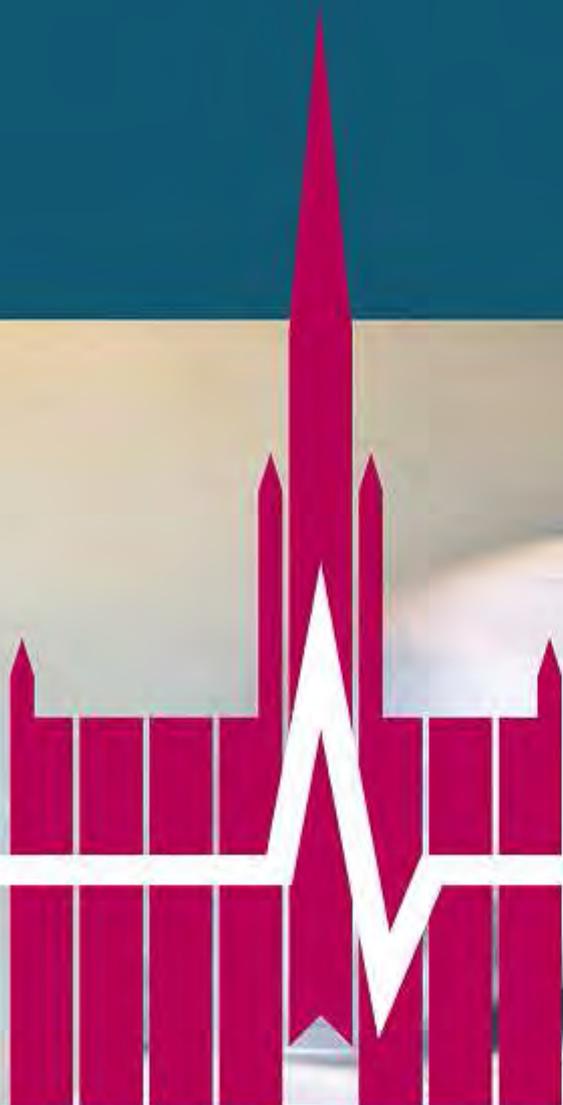


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Posters: Deadline for abstract submission: December 15, 2006

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## News World

### Clean hands leading to safer healthcare for half the world's population

<http://www.who.int/gpsc/en/>

The World Health Organization (WHO) recently announced that a total of 22 countries, representing 55% of the world's population, have signed on to the Global Patient Safety Challenge, a worldwide movement to address healthcare-associated infections, since it was launched by the WHO Alliance for Patient Safety in October 2005. Of the 22 participating countries, 10 are running hospital hand hygiene campaigns and have made an alcohol hand rub available at the point of care and 3 have set up national committees on infection control. Since the time of the WHO's announcement, 13 additional countries have committed to the initiative.

According to WHO estimates, at any given moment, some 1.4 million people worldwide suffer from infections acquired in hospitals. In developed countries, hospital-acquired infections affect 5% to 10% of patients. In some developing countries, as many as 25% of patients may be affected. Hand hygiene before care provision is one of the simplest and most powerful approaches to fighting healthcare-related infection. The WHO is encouraged by the growing commitment to clean, safer care around the world.

## News Industry

### Maquet Critical Care unveils neurally controlled ventilation technology

[www.maquet.com](http://www.maquet.com)

At the 19th Annual Congress of the European Society of Critical Care Medicine (ESICM) in September, Maquet Critical Care (Maquet) announced the launch of its latest breakthrough in mechanical ventilation, Neurally Adjusted Ventilatory Assist (NAVA). Maquet's new Servo-i ventilator with NAVA enables the patient's respiratory center in the brain to control ventilation on a breath-by-breath basis. The new NAVA technology also enables a complete evaluation of neural respiratory control via the diaphragm's electrical activity. In the words of researcher Christer Sinderby at St. Michael's Hospital in Toronto, Canada, "It offers a unique monitoring capability for the medical staff."

According to Maquet, the NAVA approach to mechanical ventilation is based on the patient's neural respiratory output. Signals from the respiratory control center in the brain are transmitted through the phrenic nerve to the diaphragm,

where a catheter captures the electrical activity (Edi) and feeds it to the ventilator. NAVA responds to this reading by providing the requested level of ventilatory support to the patient. As the ventilator and diaphragm work with the same signal, ventilation can be adjusted to the patient's needs almost instantaneously.



The electrical impulse from the diaphragm offers the first signal that a change in ventilation is needed, making NAVA a marked improvement over conventional mechanical ventilators, which sense patient effort by either a drop in airway pressure or a reversal in flow, the last and slowest reacting step in the chain of respiratory events. Maquet has identified a series of benefits associated with NAVA technology, including: improved synchrony between the patient and ventilator; increased lung protection and patient comfort through more accurate ventilatory support; and the ability to use the ventilator's Edi signal to monitor various aspects of ventilation and inform decisions on patient sedation, unloading and extubation.

At present, NAVA technology is available on the Servo-i ventilator. The only equipment required in addition to the SERVO-i ventilator is NAVA software, an Edi Module and an Edi catheter. Maquet has stated that it will be possible for existing Servo-i users to upgrade their existing system with NAVA technology.

### Dräger Medical introduces new technologies to enhance critical care

[www.draeger-medical.com](http://www.draeger-medical.com)

#### Innovian® VF4

Dräger presented its Innovian® VF4 at Medica 2006. Innovian VF4 combines Innovian Perioperative Care and Innovian Critical Care (the next release of ChartAssist®). Innovian Perioperative Care is an operating room/anaesthesia information management system that handles scheduling, pre-op, induction, intra-op and

PACU. Innovian Critical Care is an intensive care documentation system with full electronic patient charting, scoring and printed reports. Innovian VF4 integrates these systems in one, easy-to-navigate interface, allowing clinicians a more comprehensive view of the patient's care experience. In addition, Pick and Go® technology incorporates data from Infinity® monitors into the Innovian database. Clinicians may access the web-based system from anywhere within the hospital's intranet network.

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#### Infinity® TeleSmart

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\*Omato JP et al. American Heart Association Annual Meeting, 2005.  
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## Use of induced hypothermia: Acceptance and implementation issues



In this article, Professor Girbes discusses the difficulties a manager may face when introducing the practice of therapeutic hypothermia into the intensive care unit (ICU), as well as the best techniques for overcoming these obstacles. The change management techniques he recommends may help smooth the transition and ensure successful implementation.

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### Introduction

Induced hypothermia can now be considered a life-saving and neurological outcome-improving intervention. According to evidence-based medicine (EBM), this therapy must be applied after cardiopulmonary resuscitation (CPR). Induced hypothermia is also indicated for patients experiencing increased intracranial pressure (ICP) after traumatic brain injury, as a means of decreasing ICP. More indications are under investigation, and the reader is encouraged to learn more in recent reviews, such as those published by Oddo et al. and Dr. Kees Polderman (see table 1).

Despite these studies showing significant therapeutic benefits, induced hypothermia is still a relatively new therapeutic strategy, and many hospitals and intensive care units (ICUs) might not be familiar with the rapid and successful induction of hypothermia. Thus, in order to encourage effective implementation of the therapy, awareness of the therapy must be raised among healthcare professionals. Additionally, the long-standing, relatively passive attitude of healthcare workers towards post-resuscitation patients must be altered, since induced hypothermia requires a very active “*surveillance armée*” not only to apply hypothermia rapidly and successfully, but also to prevent poten-

tially dangerous side effects, which might undo the therapy’s beneficial effects. Because changing the behavior of healthcare workers, including physicians, is well known to be very difficult, great leadership skills are required to introduce such a new strategy successfully.

### Barriers for implementation

The so-called “Don Corleone” policy implementation method, in which the leadership, drawing upon their authority, present the available literature to the team, together with the small but urgent message to implement is doomed to failure, at least in the long term. Introduction of a new therapy, especially if it demands more efforts on the part of the staff, requires a careful plan that includes education, motivation and support of the team. Additionally, it is my conviction that the ownership of such a new strategy should be given to (members of) the team. This will be discussed later.

As a rule, doctors, scientists and department heads are very good at rational reasoning. When implementing a new hypothermia policy, however, one should not forget that non-rational arguments can play an important role in the behavior of these medical professionals. Staff should be reassured that the introduction of a new and better method does not mean that they previously did a lousy job, in order to ease the staff’s concerns about the change. However, changing the old behavior of doctors has proven to be extremely difficult, and patience is a virtue that is relatively rare in (ICU) doctors. Even if the evidence supporting change is strong, as is the case for induced hypothermia, well-established patterns are difficult to alter if the working environment is not conducive to change.

Examples of barriers to implementation of an evidence-based practice, such as induced hypothermia, include:

- **An unfavorable organizational context.** For example, if a treatment is not reimbursed or there is a clear lack of time, it may be impractical to implement the new procedure.
- **An inhibitive social context.** So-called opinion

*Oddo M, Schaller MD, Feihl F, Ribordi V, Liaudet L.* From evidence to clinical practice: effective implementation of therapeutic hypothermia to improve patient outcome after cardiac arrest. *Crit Care Med* 2006; 34:1865-1873.

*Polderman KH.* Application of therapeutic hypothermia in the ICU: opportunities and pitfalls of a promising treatment modality. Part 1: Indications and evidence. *Intensive Care Med* 2004; 30:556-575.

*Polderman KH.* Application of therapeutic hypothermia in the ICU: opportunities and pitfalls of a promising treatment modality. Part 2: Practical aspects and side effects. *Intensive Care Med* 2004; 30:757-769.

Table 1: Recommended reviews on induced hypothermia

leaders may play an important role in this context. If they fail to appreciate the evidence, other team members may, as well.

- **An unprepared clinical context.** Clinical uncertainty and a lack of specific skills may further impede implementation.

Acknowledgement of all these factors is the beginning of a successful route to implementation.

### **The example of hypothermia**

A brief consideration of change management for therapeutic hypothermia practices may illuminate some of the difficulties that leadership may encounter when introducing therapeutic hypothermia in the ICU. We can mirror this to the practice of hand-washing, which has a proved, major impact on hospital-acquired infections: despite all the evidence pointing to the role of hand-washing in preventing the spread of infection, the compliance of healthcare workers, especially doctors, is very poor.

Difficulties in the process of successfully introducing therapeutic hypothermia can be anticipated at varying levels:

- At an individual level (“I never saw any improvement in neurological outcome” - “I think there is a lack of hard evidence” - “The machine makes too much noise” - “I have no time for all the extra work”);
- At the level of the team or unit (“Nobody controls the correct application” - “The leadership is not interested”); and
- At the level of the hospital (“It is not feasible” - “No hospital guidelines exist” - “No facilities are available”).

Consequently, because barriers to change exist at various levels, it is important to develop and implement an induced hypothermia policy in a manner that addresses each of these possible stumbling blocks.

### **Strategies for implementation**

The supply of clear information is of the utmost importance. Such information may include educational materials, educational outreach visits, (small) conferences and interactive small-group meetings. Information transmitted by a so-called opinion leader may also contribute. Some managers tend to believe that, if the desired goals have not been achieved, giving more and more information will settle the problem, bringing achievement of the desired goal closer. However, giving information is only one aspect of a strategy for successful imple-

mentation, and it is, in general, not successful as a single intervention.

Other, more successful strategies include feedback on performance, reminders, computerized decision support (such as patient data management systems, or PDMS, in the ICU), mass media campaigns and financial interventions. Since physicians are an especially difficult target group to change long-standing, established patterns of acting, other professionals can be called in to help stimulate change. Therefore, substitution of tasks, e.g. by physician assistants or nurse practitioners, may be helpful. The highest success rate, however, is probably achieved by a combination of many of these interventions.

### **A case for giving away ownership**

An implementation strategy for the leadership that should not, in my view, be overlooked is giving ownership of the transition to a dedicated group in the team. The most important contribution of the leadership is:

- To identify members of the team who are (potentially) motivated; and
- To be willing to “give away” the honor of a successful new treatment (and its implementation) to others.

For a hypothermia project, this might mean that you ask a group of nurses and doctors to assess the value of hypothermia and – if deemed useful by them – to implement this therapy. It is important to involve “key-persons” of the ICU team in such a group, and they should be given clear responsibilities. The leadership should then give positive feedback frequently when this group makes any progress. Feedback can also be given in the form of data on the effectiveness of an intervention. For example, giving feedback on the (improved) results of survival of resuscitated patients may well continue to motivate the team, partly because the merits of this result are attributed to those who introduced a new strategy, i.e. the team members themselves.

### **Conclusion**

Introduction of a new treatment or therapeutic strategy, such as induced hypothermia, requires a careful plan. Providing information and education alone are surely not enough to successfully implement such a change. However, several tools are at our disposal and can be used to make implementation a victorious event. ■

## Therapeutic hypothermia after cardiac arrest



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In this article, Dr. Nolan discusses the benefits of induced hypothermia following cardiac arrest. He further explains the key factors that must be considered when implementing this therapy to optimize patient outcome.

Of the patients who sustain an out-of-hospital cardiac arrest caused by cardiac disease, just 7% survive to hospital discharge (Pell 2003). Survival to discharge after in-hospital cardiac arrest is 15-20% (Sandroni et al. 2006). Many of those who regain a spontaneous circulation die subsequently from neurological injury (Laver et al. 2004), which is sustained during the anoxic, no-flow period of cardiac arrest or as a result of reperfusion injury that occurs in the early post-resuscitation phase (Safar et al. 2002). Mild hypothermia in the early post-resuscitation period may prevent or reduce this reperfusion injury (Sterz et al. 2001).

Two randomized controlled trials have demonstrated that mild therapeutic hypothermia improves outcome in unconscious patients with spontaneous circulation after initial resuscitation from cardiac arrest (Bernard et al. 2002; Hypothermia After Cardiac Arrest Study Group 2002). These studies enrolled only those patients with an initial rhythm of ventricular fibrillation (VF), and the vast majority of these were out-of-hospital cardiac arrests. The larger of the two studies, which was undertaken in several European centers, randomized 273 patients to be treated with either therapeutic hypothermia (32-34° for 24 hours) or normothermia (Hypothermia After Cardiac Arrest Study Group 2002). Fifty-five percent of the patients in the hypothermia group were discharged alive with a good neurological outcome, versus 39 percent in the group who were treated conventionally ( $p=0.009$ ). The other study was undertaken in Australia and reported similar results, albeit with fewer patients (Bernard et al. 2002).

On the basis of these studies, the International Liaison Committee on Resuscitation (ILCOR) published an advisory statement recommending that "unconscious adult patients with spontaneous circulation after out of hospital cardiac arrest should be cooled to 32-34°C for 12-24 hours when the initial rhythm was ventricular fibrillation" (Nolan et al. 2003). The main recommendation was restricted to this specific group of cardiac arrest patients to reflect the highly selected group of subjects enrolled in the two clinical studies. A secondary recommendation made by ILCOR was that "such

cooling may also be beneficial for other rhythms or in-hospital cardiac arrest." Clinicians at many centers cool patients who remain comatose after cardiac arrest from non-shockable rhythms (Holzer et al. 2006), despite the lack of high-level outcome data for this group.

Generally accepted contraindications to inducing hypothermia are: severe systemic infection, severe cardiogenic shock, established multiple organ failure and pre-existing medical coagulopathy (patients given thrombolytic therapy can be cooled). There are several well-documented complications associated with the use of mild hypothermia, which need to be anticipated and managed appropriately if the post-cardiac arrest patient is to benefit from this therapy (Polderman 2004). Complications include infection (e.g. pneumonia), coagulopathy, vasoconstriction, arrhythmias (particularly bradycardia), hyperglycemia, electrolyte disorders and pancreatitis.

Shivering can occur at any time, but is particularly common during the cooling and rewarming phases. Sedation with propofol and an opioid will attenuate the problem, and buspirone may also be effective (Mokhtarani et al. 2001). An infusion of magnesium may reduce the shivering threshold and, as a vasodilator, increase the rate of cooling. If shivering persists, it may be necessary to give a bolus of a neuromuscular blocking drug. Many clinicians elect to use infusions of neuromuscular blocking drugs, but this is generally unnecessary and may mask convulsions.

Cooling should be initiated as soon as possible after return of spontaneous circulation, but appears successful even if it is delayed (e.g. 4-6 hours). Most centers will cool patients for 24 hours and then re-warm slowly at 0.25°C h<sup>-1</sup>. A significant systemic inflammatory response is very common in post-cardiac arrest patients, and considerable care is required to prevent hyperthermia, which would increase neurological injury.

Several cooling techniques exist, but none of these combines ease of use with high efficacy. External

► continued on p. 11

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# Economic impact of rFVIIa in management of perioperative bleeds in burns patients



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In addition to its more common, approved uses, activated recombinant coagulation factor VII (rFVIIa) can be beneficial to the treatment of burn injuries when excision and skin grafting are performed.

## Introduction

At the Rigshospitalet, University Hospital of Copenhagen, we conducted a pilot study which aimed at investigating the effect of rFVIIa on the reduction of blood transfusion requirements in burn patients undergoing excision and skin grafting, as a possible way to reduce the cost of blood components. The results from this study enabled us to examine the overall economic impact of rFVIIa in the management of perioperative bleeds in burn patients, as well as its efficacy and safety in patients with major full thickness burn injury undergoing the treatment. The study we conducted was a single-center, randomized, double-blind, placebo-controlled trial, which took place between June 2001 and December 2003. The local Institutional Ethics Committee approved the trial protocol, and we obtained written patient consent.

## Study design

The study focused on the total number of units of blood components transfused per patient and percentage full thickness wound excised during and up to 24 hours after surgery. Furthermore, we analyzed the operating time, the number of patients with micro-vascular bleeding, percentage graft survival on day 7 after surgery, days spent in the inten-

sive care unit (ICU) after surgery, days of hospitalization and patient survival rate on day 30 after surgery (see table 1). These observations enabled us to investigate in detail the cost of rFVIIa treatment and compare it to that of the placebo. Our study took into account 18 consecutive patients scheduled for surgery, who were randomized to receive either placebo or 40 µg/kg rFVIIa administered at first skin incision and a second dose (40 µg/kg) 90 minutes later.

## Patient outcome

The results showed that rFVIIa significantly decreased the total number of units of blood components transfused per patient and percentage full thickness burn wound excised compared with placebo (0.9 vs 2.2, p=0.0013) including significantly fewer red blood cell units (0.5 vs. 1.1, p=0.004). We further observed a trend towards improved graft survival and a reduction in multiple organ failures in the rFVIIa-treated group, possibly explained by the described association between red blood cells transfusion and infectious complications and mortality. Moreover, the number of days with sepsis was reduced in the rFVIIa-treatment group (total days: 20; mean 6.89 ±3.2) compared to the placebo group (total days: 62; mean

Table 1. Trial results

	Placebo (n=9)	rFVIIa (n=9)	p value*
Operating time (minutes)	40 (95-200)	120 (60-190)	0.76
Microvascular bleeding	4	1	0.29
Graft survival (%)	75 (65-100)	95 (65-100)	0.10
Survival (at day 30)	66.7%	100%	0.20
Time in ICU (days)	8 (0-37)	4 (0-63)	0.59
Time in hospital (days)	36 (28-72)†	49 (33-110)‡	0.22

Data are shown in median (range) when applicable.

\*Two-sample Wilcoxon rank sum test or Fisher's exact test for count data as appropriate.

†Three patients died on days 7, 20 and 20 and were excluded.

‡One patient died on day 63 and was excluded.

2.2 ± 0.8). The operating time, days spent in the ICU and days in the hospital were not significantly reduced by active treatment. Survival rate at day 30, however, considerably improved.

### Cost effectiveness

Our study showed that the mean cost of treatment using placebo or rFVIIa was similar – \$65,353 for the placebo vs. \$61,948 for rFVIIa treatment, at U.S. hospital discounted prices. Furthermore,

although the mean cost of rFVIIa used in treatment was \$7,896 (versus \$0 for the placebo), the associated reduction in the mean cost of blood components exceeded \$10,000 (see table 2). The increased survival rate for severe burn patients treated with rFVIIa implied a longer hospital stay, and thus a slightly higher hospital stay expense. Nevertheless, despite the cost similarities between the two treatment groups, the mean cost per survived patient was 33% lower with rFVIIa treatment (at \$65,308) than in the placebo group (at \$97,542).

Table 2. Mean cost of placebo vs. rFVIIa (in \$)

Resource Use	Placebo	rFVIIa
Cost of blood components	21,164	9,724
Cost of hospital stay (Inc. ICU)	38,756	43,031
Cost of surgical operations	5,433	4,657
Cost of hamostat (rFVIIa)	0	7,896
<b>Sub-total</b>	<b>65,353</b>	<b>65,308</b>
=====		
Mean cost per treatment (U.S. List Price - \$1.41)	65,353	65,308
Mean cost per survival (U.S. List Price -\$1.41)	97,542	65,308
Mean cost per treatment (U.S. Hospital Discounted Prices – \$0.81)	65,353	61,948
Mean cost per survival (U.S. Hospital Discounted prices – \$0.81)	97,542	61,948

### Conclusion

Our study at Rigshospitalet reveals the potential effectiveness of rFVIIa in the treatment of severe burn patients, and we recommend further analysis on the topic with a larger dataset and/or trial data. We are confident, however, that rFVIIa is beneficial in decreasing blood transfusion requirements for excision and skin grafting, resulting in a significant cost reduction. ■

*continued from p. 8*

cooling methods are easy to apply, but are slow in reducing core temperature. The external techniques include cooling tents; cooling blankets (using circulating water or air); ice packs to the groins, axillae and neck; wet towels and fanning; and a variety of cooling helmets. One of the fastest and simplest methods to initiate cooling is to infuse 30 ml kg<sup>-1</sup> of normal saline or Hartmann's solution at 4°C. This reduces core temperature by 1.7°C and does not cause pulmonary edema

(Bernard et al. 2003). An endovascular cooling device, inserted into the femoral vein, enables precise temperature control (Holzer et al. 2006).

Further research needs to be undertaken to determine the optimal duration of the hypothermia, the optimum target temperature, the rate of cooling and re-warming and the optimal cooling technique (external or internal). ■

# Taking the next step in medical emergency team management

Medical emergency teams responding to bedside caregiver-activated calls, triggered by deterioration in defined, continuously measured physiological variables, reduce mortality, morbidity and the cost of healthcare. However, to become universally effective, they need to develop an automated, integrated and universal monitoring system that does not require bedside caregiver input for initiation.

## ICU Stakeholder

- Anaesthesiology
- Cardiology
- Pharmacy
- Internal medicine
- Microbiology
- Nephrology
- Respiratory
- ...

Medical emergency teams (METs) are part of a hospital's rapid response system (RRS), a program to identify and respond to suddenly critically ill patients and to prevent future events. The teams (the responder component of the system) respond to bedside caregiver-activated calls, which are triggered by patient deterioration. While this deterioration is often discovered in the course of routine patient care or a patient call for a nurse, it may also be identified through continuously measured physiological variables.

When activated, METs have been shown to reduce mortality, morbidity and healthcare costs (Bellomo et al. 2003; Buist et al. 2002; DeVita et al. 2004; Tibbals et al. 2005). Implementation of the MET in these studies decreased the risk for patients to have an adverse outcome by 58% ( $p < 0.0001$ ) and reduced the duration of stay after major surgery ( $p = 0.0092$ ). Table 1 shows some of the results of the introduction of the MET.

Once initiated, RRS by MET services have been found to be cost-effective, because they reduce

length of stay and mortality and prevent ICU admissions (Garcea et al. 2004; Bellomo et al. 2004). However, RRS effectiveness may be limited by the need to have caregiver direct observation of patient behavior in order to identify factors associated with instability in the patient's condition.

Both Jones and Galhotra have reported an unexpected diurnal variation in MET activation that relates more to staffing than patient illness and may be mitigated by increased monitoring (Galhotra et al. 2006; Jones et al. 2006). These authors have opined that, for RRS to become most effective, hospitals need to develop an automated, integrated and universal monitoring system that permits bedside caregiver interface, but does not require bedside caregiver input to trigger a MET response. Continuous monitoring systems, like pulse oximetry, allow for independent patient monitoring, but account for only a limited number of physiologic variables. Additionally, monitoring artifacts are often associated with probe dislodgement and low signal-to-noise ratio, such as erratic signals and unphysiologically low  $O_2$  saturation signals from probe dislodgement, (Tsein and Fackler 1997). The systems have no capability to cross-reference other vital signs to "weed out" false alarms. Because only about 50% of crisis events are hypoxemic respiratory events (with most of the remainder being neurologic or hemodynamic deterioration), multiple physiologic variables must be monitored to accurately identify patients in crisis.

Systems that can synthesize and integrate data from a number of physiologic sources may more effectively target patients at risk. Subbe et al. (2001) implemented an Early Warning Score (EWS) to provide for more objective evaluation and synthesis of physiologic measures to identify patients at risk for deterioration. In a prospective study, they categorized data from 5 parameters (blood pressure, heart rate, respiratory rate, temperature and level of consciousness, each scored 0 to 3



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Condition	Percentage RRR	p value
Respiratory failure	79.1	<0.001
Stroke	78.2	0.0026
Severe sepsis	74.3	0.0044
Acute renal failure	88.5	<0.0001
Emergent ICU admission	44.4	0.001
Postoperative deaths	36.6	0.0178

Table 1: Relative risk reduction (RRR) following introduction of MET

Increased Incidence	Odds Ratio	95% Confidence Interval
Risk of death	5.4, 95%	2.8-10.07
ICU admission	10.9	2.2-55.6
High dependency unit admission	3.3	1.2-9.2

Table 2: Increased risk associated with EWS scores  $\geq 5$

► continued on p. 15

# Evidence-based management of acute lung injury and acute respiratory distress syndrome

This article reviews the practices that are evidence-based in managing adult patients with acute lung injury and acute respiratory distress syndrome.

## Introduction

Acute lung injury (ALI) and acute respiratory distress syndrome (ARDS) remain common causes for the admission of patients to the intensive care unit (ICU). Mortality, especially in patients with ARDS, remains high, in spite of improvements in intensive care management (Roca et al. 2006; Vasilyev et al. 1995). Several factors, such as trauma, sepsis and pneumonia, can lead to ARDS (Villar et al. 1999), and the management of these conditions will have an overall impact on the outcome of patients with ARDS, in addition to the management of acute respiratory failure (ARF). Many randomized controlled trials (RCTs) have been conducted over the last few decades to evaluate the effectiveness of practices used in managing patients with ARF. We aimed to review the practices that were evaluated by RCTs in managing patients with ALI and ARDS.

## Practices reviewed

The following practices were reviewed, and a summary is presented in table 1.

## Mechanical ventilation:

Mechanical ventilation remains the mainstay in managing patients with severe respiratory failure. However, there are several modes of mechanical ventilation and differing strategies that are used in clinical practice.

*Mode of mechanical ventilation:* The most commonly used modes are pressure controlled and volume controlled ventilation. The randomized controlled trial conducted by the Spanish Lung Failure Collaborative Group, comparing volume controlled and pressure controlled ventilation, showed a significant increase in hospital mortality (78% vs. 51%;  $p=0.02$ ), development of extra-pulmonary

## ICU Stakeholder

- Anaesthesiology
- Cardiology
- Pharmacy
- Internal medicine
- Microbiology
- Nephrology
- Respiratory
- ...



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Intervention	Comment	Reference
Pressure controlled ventilation	Reduces mortality and development of extra - pulmonary organ failures.	Esteban et al. 2000
Low tidal volume ventilation	Reduces mortality.	2000
Prone ventilation	Improves oxygenation.	Gattinoni et al. 2001
Inhaled nitric oxide	No significant benefit.	Sokol et al. 2003; Taylor et al. 2004
Surfactant	No significant benefit.	Davidson et al. 2006; Tiruvoipati et al. 2006
Corticosteroids	Routine use not recommended.	Steinberg et al. 2006
Conservative fluid management	Improves lung function and shortens duration of ventilation and ICU stay.	Wiedemann et al. 2006
Pulmonary artery catheters	Routine use not recommended.	Richard et al. 2003; Wheeler et al. 2006
Tracheostomy	Role and timing needs further evaluation in patients with ARDS and ALI. Early tracheostomy may reduce duration of ventilation and ICU stay.	Griffiths et al. 2005

Table 1: Summary of practices reviewed.

	<b>Control Group (n=45)</b>	<b>Experimental Group (n=50)</b>
Tidal volume (mL/kg predicted body weight)	9 - 11	5 - 8
PEEP	≥5 cm H <sub>2</sub> O	2 cm H <sub>2</sub> O above the lower inflection point of the pressure volume curve
ICU mortality (p = .040)	53.3%	32%
Hospital mortality (p = .041)	55.5%	34%
Ventilator-free days at day 28 (p = .008)	6.02 +/- 7.95	10.90 +/- 9.45

Table 2: Results of the Spanish study

organ failures (median 3.7 vs. 2.6; p=0.005) and renal failure (64% vs. 32%; p=0.009) among patients who were treated with volume controlled ventilation (Esteban et al. 2000).

*Ventilator settings:* Tidal volume and positive end-expiratory pressure (PEEP) settings during ventilation have been evaluated in several RCTs. The ARDS network trial, comparing lower tidal volumes (6 ml/kg) with traditional tidal volume (12 ml/kg), showed that in patients with ALI and ARDS, mechanical ventilation with a lower tidal volume resulted in decreased mortality (31.0% vs. 39.8%, p=0.007) and more ventilator-free days during the first 28 days after randomization [mean (+/-SD), 12+/-11 vs. 10+/-11; p=0.007] (ARDS 2000).

In a recent RCT, a Spanish group of investigators compared a higher PEEP / lower tidal volume ventilation (experimental group) strategy with a lower PEEP / higher tidal volume (control group) strategy in patients with ARDS (Villar et al. 2006). The study found that mortality decreased and ventilator-free days increased in the experimental group, as compared to the control group (see table 2).

Brower et al. compared the effects of high PEEP versus low PEEP in patients with ARDS, while aiming for tidal volumes of 6 mls/kg and plateau pressure of < 30 cm of water, as proposed by the ARDS network in all patients (ARDS 2000; Brower et al. 2004). The clinical outcomes evaluated (mortality; numbers of ventilator-free and ICU-free days; number of days without circulatory, coagulation, hepatic or renal failure; or the incidence of barotrauma) were similar whether lower or higher PEEP levels are used (Brower et al. 2004). These results suggest that management of tidal volume is probably more important than PEEP strategy in improving the outcomes.

*High frequency oscillatory ventilation (HFOV):* Derdak et al. compared the use of HFOV with con-

ventional ventilation in patients with ARDS (2002). Survival without the need for mechanical ventilation at 30 days was the primary endpoint. Although the use of HFOV was found to be safe, it did not improve survival without the need for mechanical ventilation at 30 days (36% and 31% in the high-frequency oscillation and conventional ventilation groups, respectively; p=0.686). Other comparisons, including hemodynamic variables, oxygenation failure, ventilation failure, barotraumas or mucus plugging did not differ significantly between the two groups.

**Prone ventilation:** Gattinoni et al. evaluated the use of prone ventilation in patients with ALI and ARDS in a randomized controlled trial (Gattinoni et al. 2001). Prone ventilation was shown to improve oxygenation with no increased incidence of adverse events. However, the effects of improved oxygenation did not translate into a reduction in mortality. Subsequently, several other investigators evaluated the effects of prone ventilation using randomized controlled trials (Guerin et al. 2004; Mancebo et al. 2006; Varpula et al. 2003; Voggenreiter et al. 2005). Based on the results of these studies, it is clear that the use of prone ventilation is associated with improved oxygenation. In the study by Guerin et al., the incidence of ventilator-associated pneumonia (VAP) was lower in patients where prone ventilation was used (1.66 vs. 2.14 episodes per 100 patient-days of intubation; p=.045) (Guerin et al. 2004). In addition, there is some evidence to suggest that prone ventilation may reduce mortality. In the study by Mancebo et al., a trend towards reduced intensive care unit mortality was noted in patients ventilated in prone, as compared to supine, position (43% vs. 58%, p =0.12). Further multivariate analysis suggests that the use of supine ventilation is associated with increased mortality (OR, 2.53; p=0.03) (Mancebo et al. 2006).

**Inhaled nitric oxide:** The use of inhaled nitric

oxide was shown to transiently improve oxygenation, but did not reduce mortality (Sokol et al. 2003; Taylor et al. 2004).

**Surfactant:** Has not been shown to reduce mortality or improve oxygenation (Davidson et al. 2006; Tiruvoipati et al. 2006).

**Corticosteroids:** A small RCT published by Meduri et al. suggested that methylprednisolone at a dose of 2 mg/kg per day for 32 days could reduce mortality and improve lung injury and multiple organ dysfunction syndrome scores (Meduri et al. 1998). However, the ARDS network trial investigating the safety and efficacy of moderate-dose corticosteroids in persistent ARDS does not support the routine use of methylprednisolone for persistent ARDS, despite the improvement in cardiopulmonary physiology (Steinberg et al. 2006). Further, the results of this trial suggest that starting methylprednisolone therapy more than two weeks after the onset of ARDS might increase the risk of death.

**Fluid management:** In a randomized study, Wiedemann et al. compared liberal versus conservative fluid management in patients with ALI. The conservative approach improved lung function and shortened the duration of mechanical ventilation and intensive care stay, but did not improve survival at 60 days (Wiedemann et al. 2006).

**Pulmonary artery catheters:** The use of pulmonary artery catheters in managing critically ill

patients has not been shown to improve outcome (Harvey et al. 2005; Shah et al. 2005). RCTs evaluating the use of pulmonary artery catheters specifically in patients with ALI and ARDS suggest that there is no benefit in terms of reducing mortality. Furthermore, there is an increased incidence of catheter-related complications, such as arrhythmias, in patients managed with pulmonary artery catheters (Richard et al. 2003; Wheeler et al. 2006).

**Tracheostomy:** The role and timing of tracheostomy is not clearly established in patients with ALI and ARDS. However, early tracheostomy (performed within seven days after admission to the intensive care unit) was shown to shorten the duration of mechanical ventilation and length of ICU stay in a group of critically ill adult patients requiring mechanical ventilation. (Griffiths et al. 2005).

## Conclusions

The management of ALI and ARDS is evolving, and evidence-based practice demands that we consider current studies to help determine which treatments produce the best patient outcome. Practices such as use of low tidal volume and higher PEEP and pressure-controlled ventilation could further improve survival. Prone ventilation and fluid restriction could be of use in patients with severe ARDS, by improving the oxygenation and prevention of VAP. Use of HFOV and the role and timing of tracheostomy in patients with ALI and ARDS need further evaluation. ■

*continued from p. 12*

(0 being normal), the total giving EWS. Table 2 on page 14 shows the results of this study, based on a cohort of 709 medical ICU patients.

Implementing the EWS system can identify unstable patients earlier (Sharpley et al. 2004). However, current non-automated systems still require direct and intermittent collection of data by clinicians, as well as intermittent calculation and reference to norms, thereby limiting their utility. Undetected deterioration may occur between assessments.

What is needed to make the MET advance to the next level of care effectiveness is a sufficiently

robust and sensitive continuous monitoring system that would work on all hospitalized patients. Data gathered continuously and analyzed by automated algorithms could then be used to activate the MET. Hopefully, the continuous data sampling and cross-referencing between parameters would provide both greater sensitivity and specificity. An "intelligent" monitoring device is likely to prevent adverse events by triggering more reliable, earlier activation of the MET. Overcoming the hurdle of "getting the team to the right spot and the right time" is likely to help reduce clinical harm and facilitate matching patients' severity of illness to the right care setting. ■

ICU Stakeholder

Anaesthesiology

Cardiology

► Pharmacy

Internal medicine

Microbiology

Nephrology

Respiratory

...

# Challenges of economic analysis of pharmaceuticals in the ICU setting: Outcomes of sedatives

Despite considerable literature on the clinical use of sedatives in the intensive care unit (ICU) population, there is limited information on pharmacoeconomics of these agents and their effects on healthcare resources (Wittbrodt 2001). In fact, most

studies are limited to an assessment of drug acquisition cost and not the total cost of care. Sedation is a typical therapeutic category in which, despite data on effectiveness, the unanswered question of “so what” remains. The goal of economic analysis of pharmaceuticals is to address these questions by showing the value of the therapy.

Key components of studies of ICU sedatives include drug acquisition costs, time to awakening after drug discontinuation, duration of mechanical ventilation, length of ICU stay and treatment of adverse drug events. The cost consequences of these variables can be ascribed. For example, we have shown that the cost of an ICU day averages \$3,500 and the incremental cost of being mechanically ventilated in the ICU is \$1,522 (Dasta 2005). Hence, a therapy that facilitates extubation will save money, even if the patient remains in the ICU. A recent program at the 2006 SCCM Congress was titled: “It’s more than just the drug costs.” The techniques used for cost analysis and the challenges in the critical care setting will be summarized here, (Cox 2006). It should be noted that these economic analyses do not make decisions; they provide quantitative data to assist in the decision-making process.

Cost minimization is the simplest technique, whereby costs of two equivalent therapies are compared and the “cheapest” is selected. One of the difficulties of this approach in critical care is documenting the equivalency of two drugs. Two sedatives may result in the same sedation scale score, but one requires more dosage adjustments and may require additional measurements of triglycerides, for example. So, the choice of the outcome of interest is crucial.

The next is cost-effectiveness analysis, which evaluates the joint economic and clinical outcomes of two therapies. It reports outcomes in units like ventilator-free days, cases of DVT prevented, and life-years saved. It is the most common and most appropriate approach in medicine today. The resulting incremental cost-effectiveness ratio between two therapies can be compared. One randomized study, for example, compared the clinical and eco-

nomic outcomes of two sedatives, propofol vs. midazolam for ICU sedation (Anis 2002). More propofol patients achieved sedation target and had a shorter time to being ready for extubation. Despite higher propofol costs, the total cost of care was not different between the two groups. This surprising finding was explained by the insufficient number of beds available to accommodate these “discharge-ready” ICU patients. So, economic studies of ICU patients must consider complicating factors, such as throughput of patients in the hospital environment.

Another common technique is a cost utility analysis, which combines both the duration of effect and the quality of the patient’s life during this time. It converts effect to “healthy years.” There is not much known about sedatives’ effects on the quality of life during an ICU stay. On one hand, propofol in high doses can “snow” the patient during their critical illness and blunt their consciousness during their ICU stay. Dexmedetomidine, an alpha-2 agonist, in contrast, causes a “cooperative sedation,” whereby the patient is easily rousable and interacts with the nurse. Relevant outcomes haven’t been quantitated by a formal cost utility study. Some data does exist on ICU patients with acute lung injury, relating the use of sedatives and neuromuscular blocking drugs to the development of post-traumatic stress disorder (Nelson 2000).

Another approach to economic analysis, particularly useful with new drugs, is a comparison of costs from a large database of patients. Since there is little information on the economics of dexmedetomidine, we compared hospital costs in post-operative bypass patients receiving this drug in addition to standard therapies from a retrospective database of 250 hospitals (Dasta 2006). We found that 356 patients receiving dexmedetomidine with midazolam plus propofol had lower total hospital charges (\$18,000), despite higher pharmacy and anesthesia charges, compared to 9,996 patients receiving only midazolam plus propofol in the absence of dexmedetomidine. The difference in total charges was due mainly to a shorter ICU length of stay. While this study is limited by its retrospective methodology, it suggests the need for a prospective randomized study.

In summary, pharmacoeconomic analysis of clinical trials is needed to document the full value of therapies. This is particularly true in the ICU, since it combines intensive “care” and intensive “costs.” ■



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# Author guidelines for ICU Management

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Articles: maximum 700 words (less if figures or tables are included)

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

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- a title;
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- website, if appropriate;
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## Thank you

**The ICU Management Editorial Team**  
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# Failure to regain weight after critical illness: a short review

## ICU Stakeholder

- Anaesthesiology
- Cardiology
- Pharmacy
- Internal medicine
- Microbiology
- Nephrology
- Respiratory
- ...

Mortality following intensive care (IC) is well reported, but morbidity information is much more meaningful for survivors. Several recent IC follow-up studies report that survivors suffer from multiple physical and psychosocial complaints (Hubble et al. 2002) and have poor health-related quality of life (QOL) (Cuthbertson et al. 2005).

Gastrointestinal (GI) symptoms have a large influence on subsequent QOL following critical illness, and failure to regain weight is a poor prognostic indicator. However, gastrointestinal function has been poorly investigated post-intensive care.

Thirty percent of patients lose more than 10kg during an intensive therapy unit (ITU) admission (Kvale et al. 2003), mainly from protein stores, and 40% are still underweight at 12 months (Galanos et al. 1997). This equates to a loss of 1% lean body mass per day (Griffiths and Jones 2002). Inadequate protein input occurs for a variety of reasons, but even if input is adequate, critically ill patients fail to adequately utilize proteins. Gastrointestinal mechanical integrity is often disturbed, and there is evidence of hormonal dysregulation involving insulin, growth hormone, steroids and, more recently, peptide YY and ghrelin (Nematy et al. 2005). Extreme catabolism and immobility in critically ill patients also contribute to the loss of total body protein.

Patients fail to regain weight immediately after discharge from intensive care. Their desire to eat is often impaired by nausea or fatigue, and there may be persistent limb weakness, breathlessness, swallowing difficulty or various malabsorptive states combined with poor provision. A host of physical and psychosocial factors influence the patient's ability to maintain their weight following critical illness (see figure 1).

IC patients may also fail to regain weight in the longer term. Forty percent of patients who spend more than four days in IC remain below their normal weight (Hubble et al. 2005). Causes can be divided into gastrointestinal and non-gastrointestinal factors.

At three months, over two-thirds of patients reported more than one symptom of GI disturbance. Poor appetite is a common complaint and may be the principal factor associated with longer-term failure to regain weight. Causes of appetite disturbance after critical illness have not been investigated. Other gastrointestinal symptoms such as dysphagia, altered taste, indigestion or change in bowel habit appear to be less common and poorly associated with persistent weight loss.

Among non-gastrointestinal factors, advancing age is highly associated with failure to regain weight. It

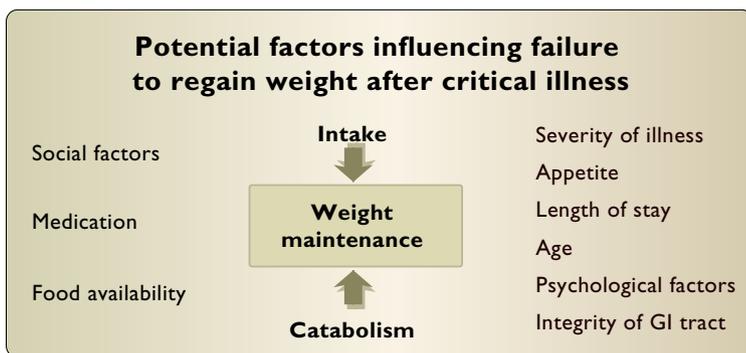


Figure 1: Factors influencing failure to regain weight

is important to note, however, that this may be because the elderly report more appetite disturbance than younger patients. Length of stay and illness severity score may have surprisingly little effect on failure to regain weight. Shortness of breath at rest, exercise tolerance and the presence of a tracheostomy are also not associated with long-term failure to regain weight.

Failure to regain weight after critical illness is common and is associated with poor survival. It is important to identify those patients particularly at risk and offer gastrointestinal investigation, as well as nutritional advice and encouragement. The causes of long-term weight loss following intensive care remain unclear, but poor appetite and advancing age are principally associated. There is no evidence to support specific dietary supplementation, but emphasis should be made on regaining muscle mass rather than increasing fat stores. Physical exercise as part of a rehabilitation program may aid this process. More research is needed to better understand the underlying causes and effective solutions for long-term weight loss. ■

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ECRI's focus is medical device technology, healthcare risk and quality management and health technology assessment. It provides information services and technical assistance to more than 5,000 hospitals, healthcare organizations, ministries of health, government and planning agencies, voluntary sector organizations and accrediting agencies worldwide. Its databases (over 30), publications, information services and technical assistance services set the standard for the healthcare community.

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ECRI is pleased to provide readers of ICU Management with sample information on products for warming/cooling units, designed for use in critical care from its Healthcare Product Comparison System (HPCS). The HPCS reports contain extensive information about the technology, its purpose, its principles of operation, stage of development specifications, reported problems and recommended specifications.

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Footnotes used in pages 20 to 23	
1. These recommendations are the opinions of ECRI's technology experts. ECRI assumes no liability for decisions made based on this data.	
2. except during high-/low- temperature condition	
3. or all nonwoven	
4. independent cardioplegia, 2-circuit heating/cooling	
5. adjustable; 420 (111), cardioplegia unitand localized heating/cooling	
6. 1,500 W (100 VAC)	
7. hydrogel layer adheres to patient's skin; redundant patient/water temperature channels; negative-pressure flow to minimize leaks; temperature out to monitor; RS232 data output; removable/remote mountable display; MRI and x-ray compatible pads.	
8. for pediatric and infant	
9. localized heating/cooling	
10. independent cardioplegia	

The data are extracted from ECRI's 2004 database and have additionally been reviewed and updated by the respective manufacturers.

## Healthcare Product Comparison System

ECRI RECOMMENDED SPECIFICATIONS <sup>1</sup>	
MODEL	FULL-BODY WARMING/COOLING UNITS
<b>WHERE MARKETED</b>	
<b>FDA CLEARANCE</b>	Preferred
<b>CE MARK (MDD)</b>	Preferred
<b>APPLICATIONS</b>	Total-body cooling/heating
<b>PADS</b>	
<b>Joint/limb</b>	
<b>Full body, adult</b>	Required
<b>Full body, child</b>	Required (pediatric)
<b>Size, cm(in)</b>	
<b>Blanket/pad material</b>	Plastic preferred
<b>Reusable/disposable</b>	
<b>MODES OF OPERATION</b>	
<b>Manual</b>	
<b>Automatic</b>	
<b>Monitor only</b>	
<b>DISPLAY TYPE</b>	Any type
<b>FUNCTION INDICATORS</b>	
<b>RESERVOIRS</b>	
<b>Number</b>	≥1
<b>Capacity, L (gal)</b>	
<b>TYPE OF FLUID</b>	
<b>FLOW, L/hr (gal/hr)</b>	
<b>Flow indicator</b>	Preferred
<b>CONNECTORS</b>	
<b>Number</b>	Varies
<b>Integral connector</b>	Preferred
<b>Strain relief</b>	Preferred
<b>TEMPERATURE SCALE READOUT</b>	Celsius and Fahrenheit preferred
<b>FLUID TEMPERATURE RANGE, °C (°F)</b>	0 to 43 (32 to 109.4)
<b>AUTO MODE PATIENT TEMPERATURE RANGE, °C (°F)</b>	3 to 37 (37.4 to 98.6)
<b>SAFETY THERMOSTATS</b>	
<b>High limit, °C (°F)</b>	≤45 (≤113)
<b>Low limit, °C (°F)</b>	0 (32)
<b>ALARMS</b>	
<b>High-temperature fluid limit</b>	Required, audible
<b>Low-temperature fluid limit</b>	Desirable, audible
<b>Patient temperature set</b>	Optional
<b>Low fluid</b>	Required
<b>H<sub>2</sub>O temperature sensor</b>	Required
<b>Patient temperature probe</b>	Required
<b>ALARM SILENCE</b>	Not recommended
<b>H x W x D, cm (in)</b>	
<b>WEIGHT, kg (lb)</b>	
<b>LINE POWER, VAC</b>	
<b>HEATER POWER, W</b>	
<b>PURCHASE INFORMATION</b>	
<b>Unit price</b>	
<b>Blanket/pad price</b>	
<b>Warranty</b>	Required
<b>Delivery tme, ARO</b>	
<b>Year first sold</b>	
<b>Number sold USA/worldwide</b>	
<b>Fiscal year</b>	
<b>OTHER SPECIFICATIONS</b>	

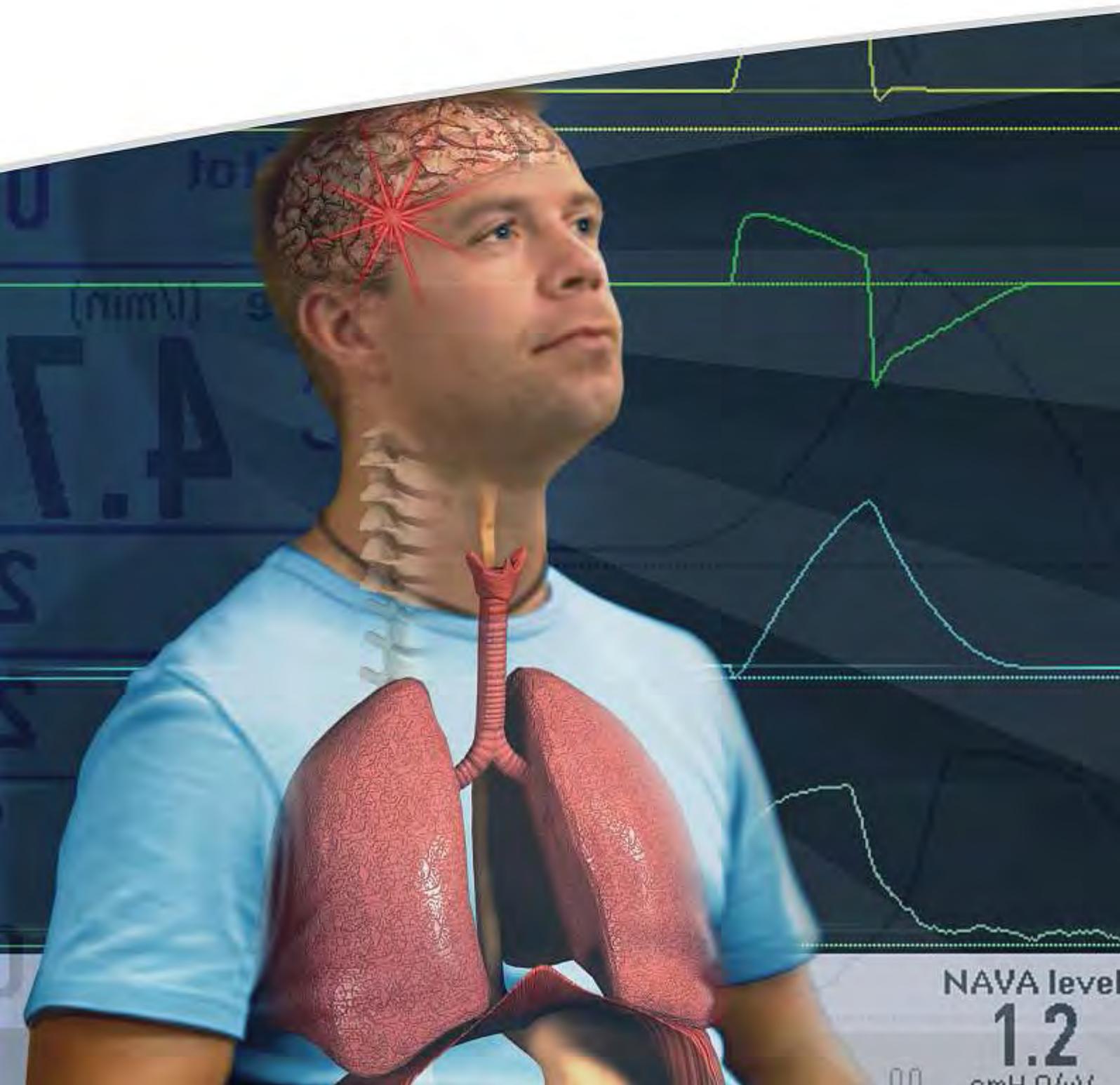
	<b>MAQUET</b>	<b>ADROIT MEDICAL SYSTEMS</b>	<b>ADROIT MEDICAL SYSTEMS</b>	<b>Gaymar</b>	<b>Gaymar</b>
	<b>Heater-Cooler Unit 30 (Jostra HCU30)</b>	<b>CTP-3000</b>	<b>HTTP-1500</b>	<b>MEDI-THERM II MTA 6012 CE</b>	<b>MEDI-THERM III MTA 6900</b>
	Worldwide	Worldwide	Worldwide	Worldwide	Worldwide
	Yes	Yes	Yes	Yes	Yes
	Yes	No	No	Yes	No
	Total-body heating/cooling, <sup>4</sup>	Localized cooling	Localized heating	Total-body warming and cooling	Total-body warming and cooling
	Yes	Yes	Yes	No	No
	Yes	Available	No	Yes	Yes
	Yes	Available	No	Yes	Yes
	Not specified	Various sizes available	Various sizes available	Various sizes available	Various sizes available
	Not specified	Fabric, foam, polyurethane	Nonwoven fabric, polyurethane	Not specified	Not specified
	Not specified	Disposable	Disposable	Reusable and disposable available	Reusable and disposable available
	Yes	Optional	Yes	Yes	Yes
	Gradient	Yes	Yes	Yes	Yes
	Remote control	No	Yes	Yes	Yes
	LCD	NA	Digital	LED	LED
	Set point (patient, cardioplegia), outlet temperature (patient, cardioplegia), ice level, patient temperature (patient, cardioplegia)	Manual	Manual	Manual, auto, monitor, alarm silence, test lights, status (flow OK, heat, in temperature, cool), set point, patient temperature, outlet water temperature	Manual, auto, monitor, alarm silence, test lights, status (flow OK, heat, in temperature, cool), set point, patient temperature, outlet water temperature, automatic cooling (gradual, moderate, rapid)
	1	1	1	2	2
	26 (6.9)	9.5 (2.6)	1.5 (0.4)	9.5 (2.5)	9.5 (2.5)
	Tap water	Tap water	Tap water	Distilled water	Distilled water
	600-1,380 (158.5-364.6) main circuit, <sup>5</sup> No, maximum pressure can be set	45 (12)	>=56 (15)	66.2 (17.5)	87.1 (23)
	No	No	Yes	Visual, audible	Visual, audible
	6 (3 circuits)	2	2	2	2
	Not specified	Yes	Yes	Not specified	Not specified
	Not specified	Yes	Yes	Not specified	Not specified
	Celsius	NA	Celsius	Celsius, Fahrenheit	Celsius, Fahrenheit
	0-41 (32-105.8)	0-21 (32-69.8)	24-41 (75.2-105.8)	4-41 (39.2-105.8)	4-42 (39.2-107.6)
	0-41 (32-105.8)	NA	NA	30-39 (86-102.2)	30-41 (86-105.8)
	42 (107.6)	NA	42 (107.6)	41.4-43.6 (106.5-110.4)	44-49 (111.2-120.2)
	NA	Not specified	NA	-3 to +3.5 (26.5-36.5)	-3 to +2.5 (26.5-36.5)
	Visual, audible				
	NA	NA	Yes	Visual, audible	Visual, audible
	NA	NA	No	Visual, audible	Visual, audible
	Visual, audible	NA	NA	Visual	Visual
	Visual, audible	NA	Yes	Visual	Visual
	Visual, audible	NA	Yes	Visual, audible	Visual, audible
	Yes	NA	NA	Visual, audible	Visual, audible
	106 x 46.5 x 52.5 (41.7 x 18.3 x 20.7)	NA	No	Yes, <sup>2</sup>	Yes
	95 (209)	28 x 34 x 23 (11 x 13.5 x 9)	25.5 x 17.8 (10 x 7)	94 x 35.6 x 47.6 (37 x 14 x 18.8)	94 x 35.6 x 47.6 (37 x 14 x 18.8)
	100-120, 220-240	2.7 (6)	2.4 (5.3)	61.7 (136)	54.9 (121)
	3,100 W (230 VAC), 1,800 W (115 VAC), <sup>6</sup>	110, 60 Hz	110, 60 Hz	220	120
		NA	180	500	500
	Not specified				
	Not specified	\$135	\$300-500	\$5,295	\$5,295
	1 year	\$15-25 each	\$5-15 each	Not specified	Not specified
	~6 weeks	90 days	1 year, limited	2 years; 5 years prorated for compressor	2 years; 5 years prorated for compressor
	2001	1-3 days	1-3 days	1-2 weeks	1-2 weeks
	Not specified	2000	2000	1999	2000
	January to December	Not specified	Not specified	Not specified	Not specified
	Automatic cleaning program; automatic emptying of external devices; pressure control and adjustable flow control; flow is shown in graphic display; 2-circuit heater/cooler system.	January to December Soft-Temp blankets and pads are latex-free. Meets requirements of UL.	January to December Redundant temperature safety limits; optional IV-pole mount. Meets requirements of UL.	January to December Separate reservoirs; visual and audible alarms; diagnostic modes; Freon-free compressor; microprocessor control with board exchange; can serve 2 blankets. Meets requirements of CUL and UL.	January to December Separate reservoirs; visual and audible alarms; diagnostic modes; Freon-free compressor; microprocessor control with board exchange; can serve 2 blankets. Meets requirements of CUL and UL.

## Healthcare Product Comparison System

	ECRI RECOMMENDED SPECIFICATIONS <sup>1</sup>	Gaymar	Gaymar	MEDIVANCE	
MODEL	FULL-BODY WARMING/ COOLING UNITS	TP472	TP500/TP500C	Arctic Sun 2000 Temperature Management System	
WHERE MARKETED		Worldwide	Worldwide	Worldwide	
FDA CLEARANCE	Preferred	Yes	Yes	Yes	
CE MARK (MDD)	Preferred	Yes	No	Yes	
APPLICATIONS	Total-body cooling/heating	Localized heating	Localized heating	Total-body cooling/heating	
PADS					
Joint/limb		Yes	Yes	Yes	
Full body, adult	Required	No	No	Torso pads	
Full body, child	Required (pediatric)	No	No	No	
Size, cm(in)		Various sizes available	Various sizes available	3 sizes	
Blanket/pad material	Plastic preferred	T-pads with polymer/nonwoven <sup>3</sup>	T-pads with polymer/nonwoven <sup>3</sup>	Foam/hydrogel	
Reusable/disposable		Reusable and disposable available	Reusable and disposable available	Disposable	
MODES OF OPERATION					
Manual		Yes	Yes	Yes	
Automatic		No	No	Yes	
Monitor only		No	No	No	
DISPLAY TYPE	Any type	Meter, analog set-point indicator	Meter, analog set-point indicator	LED/LCD	
FUNCTION INDICATORS		Lighted on/off switch, overtemperature light (activates during thermal malfunction), analog set-point dial	Lighted on/off switch, overtemperature light (activates during thermal malfunction), analog set-point dial	Manual, auto, purge, target temperature, temperature trend, time to target, precool	
RESERVOIRS					
Number	≥1	1	1	1	
Capacity, L (gal)		1.5 (0.4)	1.5 (0.4)	5 (1.3)	
TYPE OF FLUID		Distilled water	Distilled water	Distilled or sterile water	
FLOW, L/hr (gal/hr)		26.5-53 (7-14)	34.1-53 (9-14)	30-480 (39.2-107.6)	
Flow indicator	Preferred	No	No	Visual	
CONNECTORS					
Number	Varies	2	2	2	
Integral connector	Preferred	Not specified	Not specified	Yes	
Strain relief	Preferred	Not specified	Not specified	Yes	
TEMPERATURE SCALE READOUT	Celsius and Fahrenheit preferred	Celsius, Fahrenheit	Celsius, Fahrenheit	Celsius, Fahrenheit	
FLUID TEMPERATURE RANGE, °C (°F)	0 to 43 (32 to 109.4)	30-41 (86-105.8)	30-42 (86-107.6)	4-42 (39.2-107.6)	
AUTO MODE PATIENT TEMPERATURE RANGE, °C (°F)	3 to 37 (37.4 to 98.6)	NA	NA	33-37 (91.4-98.6)	
SAFETY THERMOSTATS		4			
High limit, °C (°F)	≤45 (≤113)	3.3-47.2 (109.9-116.9), 50 (122)	43.3-47.2 (109.9-116.9), 50 (122)	42.5 (108.5), 43 (109.4)	
Low limit, °C (°F)	0 (32)	NA	NA	3.5 (38.3), 3 (37.4)	
ALARMS			Visual		
High-temperature fluid limit	Required, audible	Visual	NA	Visual, audible	
Low-temperature fluid limit	Desirable, audible	NA	NA	Visual, audible	
Patient temperature set	Optional	NA	Visual	Visual, audible	
Low fluid	Required	Visual	No	Visual, audible	
H <sub>2</sub> O temperature sensor	Required	No	NA	Visual, audible	
Patient temperature probe	Required	NA	No	Visual, audible	
ALARM SILENCE	Not recommended	No	15.2 x 20.3 x 14.6 (6 x 8 x 5.8)	Yes	
H x W x D, cm (in)		15.2 x 20.3 x 14.6 (6 x 8 x 5.8)	2.3 (5.1)	76 x 32 x 56 (30 x 12.5 x 22)	
WEIGHT, kg (lb)		2.4 (5.2)	120	53 (116) with full reservoir	
LINE POWER, VAC		220	178	100/115/230	
HEATER POWER, W		178		750	
PURCHASE INFORMATION			\$475		
Unit price		\$475	Not specified	Not specified	
Blanket/pad price		Not specified	1 year	Not specified	
Warranty	Required	1 year	1-2 weeks	1 year	
Delivery tme, ARO		1-2 weeks	1996	Not specified	
Year first sold		1998	Not specified	2003	
Number sold USA/worldwide		Not specified	January to December	Not specified	
Fiscal year		January to December	Capable of serving 2 pads at once;	January to December	
OTHER SPECIFICATIONS		Capable of serving 2 pads at once; valved, leakproof cap; metal carrying handle; optional bed bracket and wheeled stands available. Meets requirements of CUL and UL.	valved, leakproof cap; metal carrying handle; optional bed bracket and wheeled stands available. Meets requirements of CUL and UL.	Energy Transfer pads are automatically shaped to cover specific areas of the body; pads have trilayer construction; pads are radiolucent and latex-free; <sup>7</sup>	

ECRI RECOMMENDED SPECIFICATIONS <sup>1</sup>	MTRE ADVANCED TECHNOLOGIES	MTRE ADVANCED TECHNOLOGIES	STOECKERT	STOECKERT
FULL-BODY WARMING/ COOLING UNITS	Allon	CritiCool	Hypo/Hyperthermia	WKS III P
	Worldwide	Worldwide	Worldwide	Worldwide
Preferred	Yes	Yes	No	No
Preferred	Yes	Yes	Yes	Yes
Total-body cooling/heating	Total-body heating/cooling	Total-body cooling/ heating	Total-body heating/cooling, <sup>9</sup>	Total-body heating/cooling, <sup>10</sup>
	No	No	Yes	No
Required	Yes	Yes	Yes	Yes
Required (pediatric)	Yes	Yes	Not specified	Not specified
	Various sizes available <sup>8</sup>	One size adult/Various sizes <sup>8</sup>	Not specified	Not specified
Plastic preferred	Nonwoven fabric, polyolefin	Nonwoven fabric, polyolefin	Not specified	Not specified
	Disposable	Disposable	Not specified	Not specified
	No	No	Yes	Yes
	Yes	Yes	Not specified	Not specified
	Yes	Yes	Not specified	Not specified
Any type	Digital	Digital	LED	LED
	Monitor, patient core temperature, patient surface temperature, flow, temperature graph, set point, energy transfer bar, heating/cooling status	Monitor, patient core temperature, patient surface temperature, flow, temperature graph, set point, energy transfer bar, heating/cooling status	Set point, water temperature, heating or cooling, water level in tank	Set point, patient; cardioplegia cold; cardioplegia warm; water temperature, patient; CP cold; CP warm; water level, patient; cardioplegia
≥1	1	1	1	3
	6 (1.6)	6 (1.6)	5.5 (1.5)	5.5 (1.5), 3 (0.9), 3 (0.9)
	Tap water	Tap water	Water	Water
Preferred	1.2 L/min (0.3 gal/min)	1.2 L/min (0.3 gal/min)	Not specified	Not specified
	Visual	Visual	Not specified	Not specified
Varies	2	2	4 (2 circuits)	6 (3 circuits)
Preferred	Yes	Yes	Not specified	Not specified
Preferred	Yes	Yes	Not specified	Not specified
Celsius and Fahrenheit preferred	Celsius and Fahrenheit	Celsius and Fahrenheit	Celsius	Celsius
0 to 43 (32 to 109.4)	13-40.8 (55.4-105.4)	13-40.8 (55.4-105.4)	1.5-47 (34.7-116.6)	2-41(35.6-105.8)
3 to 37 (37.4 to 98.6)	30-40 (86-104)	30-40 (86-104)	NA	NA
≤45 (≤113)	44 (111.2)	44 (111.2)	41 (105.8)	42.5 (108.5)
0 (32)	10 (50)	10 (50)	2 (35.6)	1.5 (34.7)
Required, audible	Visual, audible	Visual, audible	Visual, audible	Visual, audible
Desirable, audible	Visual, audible	Visual, audible	Not specified	Not specified
Optional	Visual	Visual	NA	NA
Required	Visual, audible	Visual, audible	Visual, audible	Visual, audible
Required	Yes	Yes	Not specified	Not specified
Required	Visual, audible	Visual, audible	NA	NA
Not recommended	Yes	Yes	Yes	Yes
	94 x 26 x 62 (37 x 10.2 x 24.6)	94 x 26 x 62 (37 x 10.2 x 24.6)	84 x 50 x 55 (33.1 x 19.7 x 21.7)	84 x 50 x 55 (33.1 x 19.7 x 21.7)
	33 (77)	33 (77)	90.5 (199.6)	90.5 (199.6)
	120/230	120/230	220-240	220-240
	500	500	2 200	1,600 patient, 800 cardioplegia
	N/A	N/A	Not specified	Not specified
	\$70-120	\$70-340	Not specified	Not specified
Required	15 months	15 months	1 year	1 year
	14 days	14 days	4 weeks	4 weeks
	2001	2004	1994	2000
	Not specified	Not specified	≥1,200	≥600
	January to December	January to December	January to December	January to December
	Meets Requirements of UL.	Meets requirements of UL.	Each water circuit has separate pump; separate icebox available for additional cooling efficiency.	Each water circuit has separate pump; separate icebox available; independent water tanks for patient temperature control; cold/warm cardioplegia; rapid change for cardioplegia from warm to cold or vice versa.

# IMPROVED SYNCHRONY INTRODUCING SERVO-i WITH NAVA



NAVA level

1.2

cmH<sub>2</sub>O/lit

# MAQUET

## CRITICAL CARE

**Pmean**  
(cmH<sub>2</sub>O)

**PEEP**  
(cmH<sub>2</sub>O)

**RR** (b/min)

10  
**18**

**O<sub>2</sub>**  
(%)

**Ti/Ttot**

**MVe** (l/min)

**C**  
**4.7**

**VTi**  
(ml)

28

**VTe**  
(ml)

28

**Edi peak**  
( $\mu$ V)

1

**Edi min**  
( $\mu$ V)

0

Additional  
values

**MAQUET is proud to announce a revolutionary ventilation application: NAVA (Neurally Adjusted Ventilatory Assist) – a new option for SERVO-i.**

This breakthrough technology employs Neurally Controlled Ventilation that allows the patient to control breathing patterns and tidal volumes. By using the same input signal as the diaphragm, SERVO-i provides respiratory unloading in synchrony with the patient's respiratory efforts.

Experience the predictive power of neural monitoring. Obtain enhanced knowledge for informed clinical decisions to achieve optimal conditions for the patient.



*The product may be pending regulatory approvals to be marketed in your country. Contact your MAQUET representative for more information about SERVO-i with NAVA, or go to: [www.maquet.com/nava](http://www.maquet.com/nava)*

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MEMBER OF THE GETINGE GROUP

# Quality management system in the ICU



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## Quality initiatives and concepts

Established quality and confirmed quality improvement in healthcare are not givens but the result of meticulous efforts. Many healthcare professionals have worked toward quality improvement intuitively for ages, but often without a clear idea of how to proactively set goals and follow up on outcomes. This is particularly true for the intensive care environment, which is inherently complex, prohibitively expensive and constantly changing to keep pace with the fast progression of science and state-of-the-art practice. Unfortunately, while general principles of quality management should be easily understandable for any provider, current systematic quality concepts and terminology may appear vague, mysterious or strange to the practicing clinician.

Unlike some other methods, a quality management system consistent with ISO 9001 standards has a clear dedication to a process-oriented approach that may be easily translated into the common culture, thinking and behavior of healthcare professionals. Because ISO 9001 standards

apply to all industries globally, the ISO vocabulary is not particularly user-friendly for healthcare professionals. Nevertheless, healthcare, like other modern industries, provides services, which should be courteous, efficient and effective. An ISO 9001 quality management system can help define and track these qualities in a measurable way.

## Quality management system

Quality management builds on the common steps of management in a circular advance – plan, do, check, act and start again – and includes all activities that a provider carries out to implement a quality policy. It should not require a separate administrative structure but should support and enhance the given organizational structure, with its ordinary pattern of responsibilities, authorities and relationships that control how people perform their functions and interact with one another.

## Plan

Essentially, quality is all about meeting performance requirements, such as needs, expectations

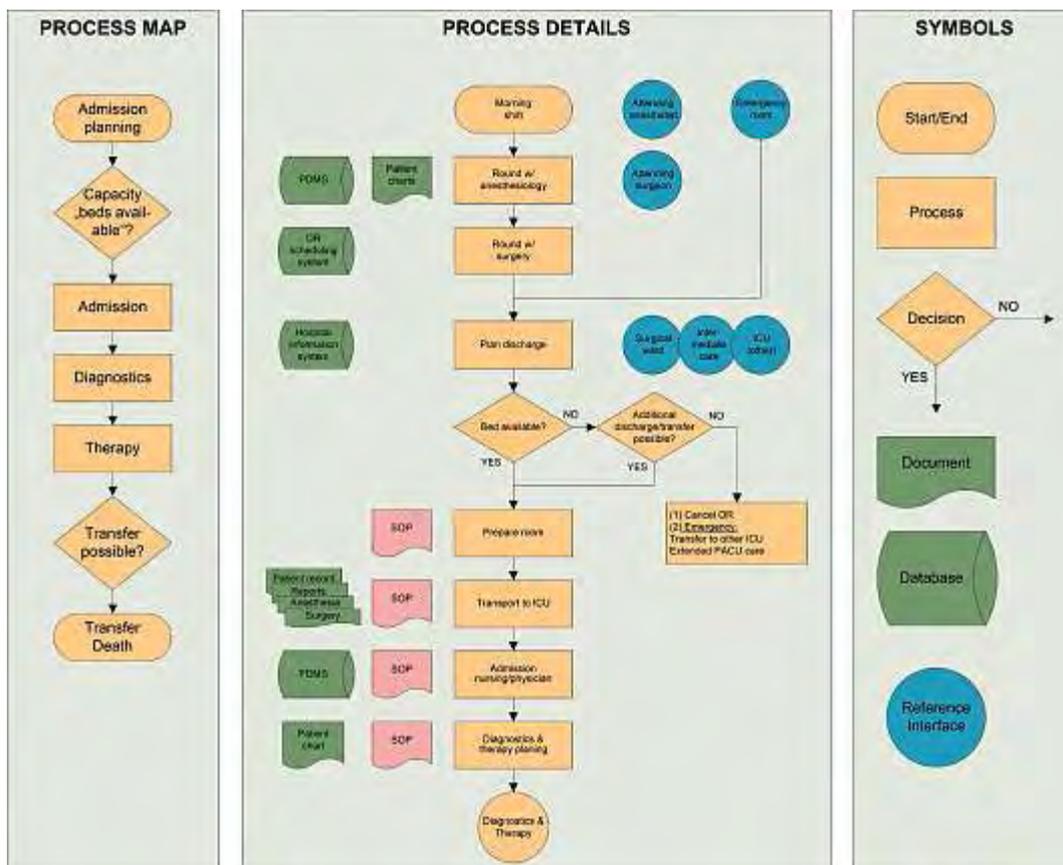


Figure 1: Consider the stakeholders' expectations

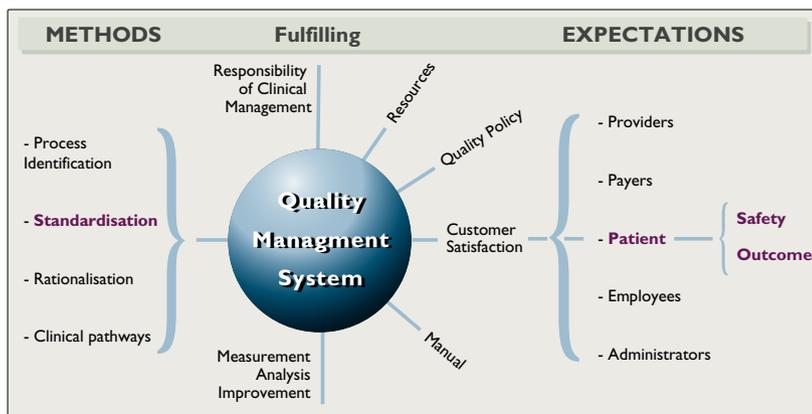


Figure 2: ISO 9001 modular approach to quality management

or obligations which are acknowledged in advance by all stakeholders involved in the process of delivering intensive care services (see figure 1). It may be practical to refer to the requirements of both internal customers (patient, surgery, anesthesiology, hospital administration, etc.) and external customers (insurance payers, suppliers, local or regional society bodies). A quality policy statement describes an organization's commitment to quality. A quality plan explains how a provider intends to apply the quality policy, achieve quality objectives and meet quality system requirements. A quality manual documents an organization's entire quality management system and should be available to employees at all times.

## Do

One advantage of an ISO 9001 quality management system is its ability to subdivide, design, describe and measure processes in a modular approach (see figure 2). Processes, whether productive or administrative, use resources to transform inputs into outputs through some kind of work, activity or function. Many processes are interconnected by multiple input-output relationships. Provision of intensive care to the patient is the key process for any intensive care provider. However, many supporting activities can be thought of processes as well: purchasing supplies; documentation and record keeping; writing, providing and updating documents; planning, scheduling and staffing; training and education; internal communication; customer communications with patients and relatives; and many more.

A standard is a documented set of rules that control how people develop and manage services, products, materials, technologies, processes and systems. ISO refers to standards as agreements, because all parties involved must agree on content and give formal approval before the standard is published. Standard operating procedures (SOPs)

control practical processes or activities, including the associated inputs and outputs. An SOP defines the work or activity and explains how it should be done, who should do it and under what circumstances it should be done. In addition, it explains what authority and what responsibility has been allocated, which supplies and materials should

be used and which documents and records must be used to carry out the work.

## Check

Monitoring of a quality management system is accomplished with internal and external quality audits. Quality audits examine the elements of a quality management system to evaluate how well these elements comply with the local quality system requirements and identify improvement opportunities. Internal quality audits are carried out on a regular basis by the provider's own personnel. External quality audits are conducted by a qualified, independent third party. External quality audits examine the elements and results of the whole quality management system in order to evaluate how well these comply with general quality system requirements, such as ISO standards. Certification and accreditation confirm that the quality management system as a whole complies with these standards.

## Act

The executive part of a quality management system mainly consists of corrective and preventive actions. Corrective actions are steps that are taken to remove the causes of an existing nonconformity or to make quality improvements. Preventive actions are steps that are taken to remove the causes of potential nonconformities or potential problems that have not yet occurred. In general, corrective actions solve problems, and preventive actions analyze and manage risk.

## Infrastructure and resources

Quality in healthcare does not come for free. Serious quality efforts require investments in infrastructure, such as workspace, hardware, software and utilities, and resources, such as people, money, technologies and information. Quality management should aim to save resources in the long

► continued on p. 44



# The use of simulation as a tool for improving team skills

Teamwork in time-critical and high stake settings is challenging and often deficient. Improved teamwork has been shown to improve treatment quality and safety.

## Introduction

Intensive care medicine is characterized by a need for time-critical decisions and interventions, often in cooperation with changing co-workers. Available research indicates that many highly skilled professionals are unable to interact and function as a team, but it is possible to improve teamwork by training.

Intensive care personnel training has, so far, largely focused on psychomotor skills and task management. Collecting a group of highly skilled professionals does not secure a well functioning team. In aviation, simulation has been used for training leadership, cooperation and communication in a team setting for years.

## Simulation and team training

Simulation encompasses activities in which real life is replicated and is useful for a number of educational activities, both for individuals and teams. Team training was initially a mixture of skills training and crisis management. Teams are now trained using carefully planned educational activities. Team training should be based on an analysis of the training objective. The competencies of the personnel involved should be assessed before training to determine the appropriate training level. On the basis of this, the goal of the training can be determined. Scenarios may be made either from real patient cases adapted to the training setting, or developed according to the need of the training goals. It is wise to make flexible scenarios, which can be adapted to different possible choices made by the team in training.

Team training may take place in simulator centers or in real-life treatment areas. It has been debated whether one needs to employ high fidelity simulators, or if less can do. This should be decided after careful analysis of the educational goals. Team training with simulation may be done with the trainees' ordinary colleagues or with strangers. Participants may play their own professional role during simulation or roles may alternate. If the main goal is to train seldom-assembled teams (e.g. trauma teams) in teamwork, they should probably play their own professional roles, as close to real life as possible. It can be useful to video-record trainees or to use systematic recording of behavioral markers during the simulation.

## Assessment and debriefing

Team training and simulation has to be assessed to order to permit feedback to the team. This should be an integral part of the planning before simulation takes place. On the other hand, doing formal assessments of professional competency during team training seems to be difficult and may also hinder participation, especially from physicians.

Learning takes place mainly after the simulation, when the team and the facilitator are reflecting on what happened during simulation. This is the most important and demanding phase of team training. Our experience is that teams shielded from non-participating observers in a supportive environment are able to do a large part of the debriefing themselves, when carefully guided. During debriefing, all participants should be encouraged to speak up, and the group should define improvement areas for a second training session.

## Organizational framework for team training

Team training is so far in its early phases in hospitals, although it has been used for decades in the aviation industry. The organization's attitude and culture are important in achieving full benefit from training. Leaders should be supportive to training; the cooperation of all departments involved is important, and transfer of knowledge from simulations to real life should be facilitated by easing the implementation of experience gained during training into clinical practice.

## How to start – where to go?

Before setting out for team training, it is necessary to define the training goals. After an analysis of the desired outcome, one should define the present skills and knowledge status of the trainees. Then, it is possible to choose educational strategies. Measurements or assessment instruments should be defined when scenarios are developed, and learning should be guided carefully. This demands cooperation between expertise in the medical field in question and educational expertise. Feedback must be given to training participants, emphasising the educational goals. This concerns the team as a whole, but often also individuals. Our experience is that two repeated simulations, with increasing complexity based on initial performance, are appreciated by the trainees. The training activities should be evaluated, not only on the day of training, but over the course of time to assess impact on the original goal. ■

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# ICU design of the future: Focus on flexibility

## Introduction

Designing an intensive care unit (ICU) to handle the needs of critically ill patients in the future requires both an ability to predict which of today's health-care trends will still be influential 20 years from now and the flexibility to adapt to these trends. Two current trends that are likely to remain current are: using resources efficiently and meeting the expectations and needs of patients' families.

## Reorganizing the resources of the hospital

The hospital of the future will feature a substantial increase in high-dependency care beds (intensive care, intermediate or step-down/step-up care and intensive monitoring) at the cost of traditional hospital wards. This transition will require maximal flexibility in design.

For the past ten years, designers and hospital representatives in Bern, Switzerland, have been planning the construction of a new facility to house 1,200 of the more than 6,000 workers employed by the University Hospital Bern (Inselspital), a tertiary referral academic medical center and Level 1 trauma center located in the Swiss capital. One of the goals of the building project is to optimize patient care by consolidating related services. In 2010, the hospital's Department of Intensive Care Medicine will move into the new building, where it will be located on the top floor, directly above the operating rooms, the emergency department, and radiology and nuclear medicine, each on their own floor. This layout will enable rapid transportation between the key acute service departments, through dedicated elevators designed for the transport of unstable patients with a maximum amount of medical devices.

## Optimizing the resources of the ICU

The ICU of the future will emphasize horizontal, multidisciplinary care and communication processes. The Inselspital's new 3,300-square-meter ICU will also incorporate features designed to improve patient care through efficient use of resources. The ICU itself has been designed to provide flexibility in patient care areas, with several different patient room configuration options, free positioning of the patient bed within the rooms and a logistics concept based on daily replacement of supplies through mobile units with predefined contents, rather than replacement of individual disposables. In addition, recent developments in information technology have been incorporated both at the bedside and in the infrastructure of the building.

Wireless communication between patient-specific bedside devices and the clinical information management systems adds flexibility to the bedside design of care areas.

## Adapting to meet new requirements

Not only is flexibility of design elements required, but flexibility in the design process is required, as well. In the ten years since the planning of Bern's new facility began, many aspects of the project have changed. The emphasis has shifted from designing a building and rooms to designing care processes (Regli and Takala 2006).

## Meeting the needs of the family

One important aspect of future design will be finding a balance between highly efficient care processes and the expectations and needs of patients' families. Already in 1992, the priorities for the design of a new critical care unit at the University of Wisconsin included "patient rooms of sufficient size..." and "a family waiting room to accommodate at least two visitors for each bed" (Hall et al. 1992). Research into the needs of the families of critically ill patients shows that the lack of a comfortable, private space for discussions and conferences is viewed as a serious drawback in an ICU (Heyland 2002).

The needs of families have been taken into account in the design of the new, Inselspital ICU. Thanks to the flexible floor plan, it will be possible to have privacy at the bedside when needed, without compromising patient safety. The unit will include comfortable areas to accommodate families at times when they do not have access to the patient. And finally, the new ICU will incorporate the recommendations of families of deceased patients in a "room of peace" designed to give families a private space to mourn after a patient has died.

## Conclusion

Twenty years ago, a hospital in Texas reported on "the development of an intensive care unit that would meet the demands of the future" (Consolvo and Coutts 1984). Although there has been almost no research into the effects of design on ICU care, design is still an issue 20 years later. Whether efficient resource use and family and patient comfort and privacy will remain design issues 20 years from now is uncertain. But the designers of future ICUs can bet on one thing: they can always profit from a measure of flexibility. ■



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## Enhancing ventilation monitoring: An interview with **Professor Ola Stenqvist**

Professor Ola Stenqvist is a Consultant Anesthesiologist in the Department of Anesthesia at Sahlgrenska University Hospital in Gothenburg, Sweden, and a professor in the Department of Anesthesiology and Intensive Care at Gothenburg University. Professor Stenqvist recently developed two, new ventilation monitoring technologies now produced by GE Healthcare, SpiroDynamics and FRC INview.

### **What research interests led you to develop SpiroDynamics and FRC INview?**

My primary research interests include the monitoring of gas exchange and pulmonary function. I also maintain a particular interest in acute lung injury and acute respiratory distress syndrome. Since the 1980s, I have been working with Datex monitoring systems. I have been particularly interested in trying to reduce the lead-time necessary when conducting research. I felt that it would be ideal to use standard monitoring systems for research. Traditional, static measurement systems create a paradoxical situation: clinicians have to stop the ventilation process in order to study the process. I thought it would be better all around if we didn't have to stop the process after all. This inspired the development of SpiroDynamics and FRC INview.

### **What do SpiroDynamics and FRC INview do?**

SpiroDynamics enables critical care specialists to monitor tracheal pressure and intrinsic PEEP measurements continuously, regardless of the ventilator setting. These measurements are captured using a disposable catheter, which can be easily inserted into standard endotracheal and tracheostomy tubes. Measurements are then taken near the end of the tube, in the trachea, and are used for calculation of lung compliance at the beginning, middle and end of each breath, so the clinician gets a more accurate view of tracheal pressure,

PEEP, and compliance at different levels of the breath.

FRC INview provides cycled, automatic functional residual capacity (FRC) measurements without interrupting ventilation. FRC INview is also able to directly measure the end expiratory lung volume, without need for an additional gas source. With this technology, critical care specialists can run a single procedure, or a series of procedures. They can even program the start of a sampling process, establish a series of measurements and compare current measurements with past measurements.

### **What difference will these technologies make in the practice of ventilation?**

SpiroDynamics and FRC INview will make a big difference for both researchers and practicing physicians. In an ideal setting, a clinician can see patient data real-time, in the ICU. These new solutions are easy to use and make data available right away, saving valuable time. In a clinical setting, real-time data on lung pressure allows the clinician to adapt ventilation to the patient's current situation, improving patient outcome.

Previously, there was no practical way to measure this in a clinical setting. SpiroDynamics and FRC INview adapt old technology to enable clinicians to measure lung pressure continuously and lung volumes automatically hour after hour, if they want to. Physicians no longer need to rely on subjective visual observations when determining how to treat their mechanically ventilated patients. SpiroDynamics and FRC INview really are a "window" into the lungs.

### **What are your plans for future research?**

I hope to continue improving ventilation monitoring possibilities. I will also continue to look for new ways to help interpret information, enabling clinicians to do more with the data available. There are always improvements to be made. ■





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## Do we need doctors to go out in emergencies?

Some national emergency systems regularly send specially trained doctors (often anesthetists) out of the hospital in emergencies (e.g. Germany and France), while other systems mainly are managed without this option (e.g. the U.S.). If one is in the position to choose which option to adopt, I would argue that there are reasons to carefully consider whether it's a wise decision to use anesthetists in such emergencies.

### What is important in pre-hospital emergencies?

Although the scientific basis for our current pre-hospital emergency care is relatively scanty, there seems to be agreement on some issues. Rapid response in both trauma and medical emergencies, with short on-scene time, is essential in all emergencies. Only life-saving procedures should be performed (safely) on-scene, and assessment of the patient and situation (situational awareness, including safety) are key factors for success. Airway management must be mastered, but should be as minimally invasive as possible. With respect to Advanced Cardiac Life Support (ACLS), perfect chest compressions, timely defibrillation, 12-lead ECG and medication (including thrombolysis if appropriate) and optimal post-resuscitation care are important. Further, hemorrhage control and volume therapy, if indicated, and the avoidance of hypothermia are critical to pre-hospital emergency care. Last but not least, emergency response personnel must be able to re-assess and evaluate the patient and possess knowledge of other, non-medical resources and skills (e.g. use of radio communication, how to cope with hostile environments, police and rescue personnel and techniques). This requires sound, thorough education and training, but competency in these areas can be achieved by health personnel other than doctors, such as ambulance staff and nurses.

### Arguments against doctors going out in emergencies

First of all, it must be acknowledged that there are some emergency situations in which the competence of a trained anesthetist is vital for the patient (e.g. the difficult airway). However, the incidence of such cases is fairly low, and there seems to be a general need for anesthetists inside the hospitals in many regions of the world. With respect to airway management, recent findings suggest that endotracheal intubation is often not the best

option, because it is difficult, and other, less invasive techniques involving supra-glottic devices have been introduced to minimize risks during intubation.

With that in mind, the most important arguments against sending specialized doctors out in emergencies are: the limited availability of competent physicians, competing in-hospital interests (e.g. medical emergency teams), the higher costs of employing physicians relative to other personnel and the local Emergency Medical Service (EMS) organization at large. It is also important to take a close look at the total pre-hospital chain of survival, emergency setting (urban or rural), strength of physician control and support to the dispatch/ambulance response system and the degree to which primary care physicians get involved in out-of-hospital emergencies. In urban areas, rapid transport of the patient to a nearby hospital, where the resources are far better than those available out in the streets, is often possible. The scoop-and-run philosophy obviously has merit in such settings. Studies have also demonstrated that specialized doctors tend to prolong the on-scene time. In the rural setting, however, the specialist may receive the patient in the hospital too late for effective intervention, if the quality of the pre-hospital services is poor. Therefore, the presence of a trained and interested general practitioner could greatly enhance rural emergency medical services.

It is possible that the specialized doctor's knowledge could benefit more patients (both within and outside the hospital) if he or she were available on-line for the paramedics. For example, it has been shown that on-line radio support from specialized doctors can be used to help ambulance personnel safely perform pre-hospital thrombolysis. Even without on-line support, workarounds can be developed. For example, venous access can be difficult

► continued on p. 43

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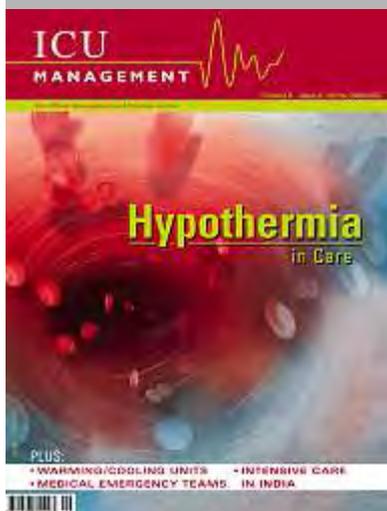
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# Committee of the Regions



**Ilze Raath**  
Editor European Affairs

The Committee of the Regions (COR or Committee) was created by the Maastricht Treaty in 1992 and provides a forum for local and regional authorities on issues affecting them. It is an advisory body that ensures public authorities are consulted on European Union (EU) proposals of direct interest to them, especially as they are often responsible for implementing these policies. Its work is organized through six commissions, which examine the details of proposals and then draw up a draft opinion, which highlights where there is agreement with the European Commission's (Commission) proposals and where changes are needed.

## Members of the COR

The COR is made up of 317 members and 317 alternate members, representing local and regional government from the 25 EU Member States, as specified by the Maastricht Treaty. Consequently, members represent the whole sphere of sub-member state government throughout Europe, including regions, provinces, counties, municipalities and districts.

In 2001, the Treaty of Nice stipulates that the number of the COR's members may not exceed 350 and includes guidance on the number of COR members allocated to each member country. COR members and alternate members are appointed for four years by the Council, acting unanimously on proposals from the respective member states.

The Treaty of Amsterdam (1997) stipulates that no member of the Committee of the Regions may at the same time be a Member of the European Parliament. Furthermore, election to the COR depends on whether the candidate in question holds a regional or local electoral mandate or is politically accountable to an elected assembly.

## Responsibilities of the COR

The COR was established to address two main issues. Firstly, seeing that three-quarters of EU legislation is implemented at local or regional level, it would make sense for local and regional representatives to have a say in the development of new EU laws. Secondly, there were concerns that the public was being left behind as the EU was busy expanding and increasing its power. By involving the elected level of government closest to the citizens, the gap was being closed.

The Treaties (Nice and Maastricht) oblige the Commission and Council to consult the COR whenever new proposals are made in areas that have repercussions at regional or local level. The Treaties set out the following areas:

- Economic and social cohesion
- Trans-European infrastructure networks
- Health

- Education
- Culture
- Employment policy
- Social policy
- Environment
- Vocational training
- Transport

The Commission, Council and European Parliament have the option to consult the COR on issues not covered by the above-mentioned factors if they see important regional or local implications to a proposal. The COR can also draw up an opinion on its own initiative, which enables it to put issues on the EU agenda. The COR's function is purely advisory.

## Political objectives

At its 63rd plenary session, the political objectives for the term 2006 through 2008 were adopted. They are:

- Strengthening the political and citizen's Europe;
- Strengthening territorial solidarity within the European Union; and
- Consolidating the political and institutional role of the COR.

## Organization and structure

The constituent bodies of the Committee of the Regions are as follows:

### Plenary Assembly

The Committee meets as a Plenary Assembly, and its main tasks are: adopting opinions, reports and resolutions, draft estimates of expenditure and revenue of the Committee and the political program of the Committee; electing all the members of the Bureau; setting up commissions; and adopting and revising the Rules of Procedure of the Committee.

### Presidency

The President directs the work of the Committee. The Committee elects the President from among the members for a two-year term.

### Bureau

The Bureau is responsible for implementing the

COR's political program. The Plenary Assembly elects the Bureau for two years. It consists of the President, the first Vice-President, one Vice-President per Member State, 25 other members and the chairmen of the political groups (56 members in total).

### **Commissions**

At the beginning of each four-year term, the Plenary Assembly sets up commissions to prepare its work. The compositions must reflect the national composition of the Committee. The commissions specialize in particular policy areas:

- Commission for Territorial Cohesion Policy (COTER)
- Commission for Economic and Social Policy (ECOS)
- Commission for Sustainable Development (DEVE)
- Commission for Culture and Education (EDUC)
- Commission for Constitutional Affairs and European Governance (CONST)
- Commission for External Relations (RELEX)

The commissions draw up the draft versions of opinions and resolutions, which are submitted to the Plenary Assembly for adoption.

### **Secretariat-General**

A Secretariat-General, headed by the Secretary-General, assists the Committee. The Bureau ensures that the COR and its constituent bodies function efficiently, by helping the members of the Committee in carrying out their duties. It draws up the minutes of the meetings of the Committee's constituent bodies. The Secretary-General is responsible for giving effect to the decisions taken by the Bureau or the President. In preparation for Bureau decisions, the Secretary-General draws up discussion documents and recommendations for a decision on each item up for discussion.

### **National delegations**

The members and alternates from each Member State form a national delegation. Each national delegation is responsible for adopting its own internal rules and electing a chairman. Members and alternates may also form interregional groups.

### **Political groups**

Four political groups are represented in the COR, which reflect the main European political families: the Party of European Socialists (PES), the European People's Party (EPP), the European Liberal Democrat and Reform Party (ALDE), and the European Alliance (EA). These groups provide a

forum for Committee members to discuss key political issues and reach common positions.

### **Execution of duty**

The Committee of the Regions is convened by its President at the request of the Council or the Commission, but it may also meet on its own initiative.

### **Work of the commissions**

The Bureau assigns requests for opinions (provided for in the annual work program) as well as requests for opinions on documents not contained in the work program to the responsible commission. In urgent cases, the President may designate a commission to deal with the specific matter. If the subject of an opinion requires input from more than one commission, the Bureau designates a lead commission and, where necessary, one or more supplementary commissions.

If the commission concerned cannot draw up a draft opinion by a certain deadline, the Bureau may propose that the Plenary Assembly appoint a rapporteur-general, who submits his draft opinion straight to the Plenary Assembly. Draft resolutions or applications for the drafting of a resolution may be submitted to the Committee by a group of at least 32 members or a political group.

The commissions present their draft opinions before the deadline set by the Bureau. If the commission thinks that a document referred to it by the Bureau has no regional or local interest, or political importance, it may decide not to draw up an opinion.

### **Plenary Session**

The draft opinion (or draft resolution) is debated and voted on during the Plenary Assembly. When a deadline cannot be met under the normal procedure and the commission has adopted its draft opinion unanimously, the President transmits this draft opinion to the Council, Commission and European Parliament for their information. The draft opinion is submitted to the following Plenary Session for adoption without amendment.

The Committee's official opinions, as well as any communication related to the use of a simplified procedure or a decision not to draw up an opinion, are sent to the Council, Commission and European Parliament. As in the case of resolutions, they are forwarded by the President. ■

# Healthcare scenario in India

India, a country with a centuries-old heritage of medical science, first became familiar with the modern systems of medicine in the 17<sup>th</sup> century. India became an independent nation in 1947 and became a Federal Republic in 1950. There have been various developments in the health sector in the post-independence era. But problems like higher population density, low socio-economic status of a significant number of people and low literacy rate in some parts of the country, have resulted in poor health indicators.



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I acknowledge the contribution of Dr. Biju Soman, Asst. Professor, AMCHSS, SCTIMST in writing this article.

## Historical background

India has a rich, centuries-old heritage of medical and health sciences. The approach of the ancient Indian medical system was one of holistic treatment. The history of healthcare in India can be traced to the Vedic times (5000 BCE), in which a description of the Dhanwanthari, the Hindu god of medicine, emerged. Atharvaveda, one of the four Vedas, is considered to have developed into Ayurveda, a traditional Indian form of holistic medicine. The philosophy of Ayurveda, "Charaka Samhita" (the famous treatise on Medicine compiled by Charaka), and the surgical skill enunciated by Sushruta, the father of Indian surgery, bear testimony to the ancient tradition of scientific healthcare amongst the Indian people. Historically, the most outstanding hospitals in India were those built by King Ashoka (273-232 BCE). Medicine based on Indian medical principles was taught in the Universities of Taxila and Nalanda.

## Transition from traditional to modern medicine

Ayurveda applies the Thridhosha theory of disease. Thridhosha describes three dhoshas, or biological elements, which are linked to a patient's health: Vata (wind), Pitta (gall) and Kapha (mucus). Disease is explained as a disturbance in the equilibrium of the three dhoshas, a concept similar to the theory put forward by Greek medicine. Other non-modern systems of medicine, like Unani and homeopathy, are not of Indian origin, but are popular in India even today.

During the 17<sup>th</sup> and 18<sup>th</sup> centuries, there was a slow and steady growth of the modern system of medicine in India, starting with the arrival of European Christian missionaries in South India in the 17<sup>th</sup> century. In 1664 at Chennai, the British opened the first modern hospital for soldiers and, in 1688, another for the civilian population. Organized medical training began with the opening of the first medical college in Calcutta in 1835, followed by a

school in Mumbai in 1845 and one in Chennai in 1850.

## Health scenario

Over the past decade, healthcare services available in India have increased dramatically (see table 1).

The doctor-to-population ratio in India is 1:2148. The infant mortality rate is 64 per 1,000 live births. The overall mortality rate has declined from 27.4 in 1991 to 8 per 1,000 population in 2002, and life expectancy at birth has increased from 37.2 years to 60.6 years over the same time period.

Since independence, considerable progress has been achieved in the promotion of health in India. Smallpox has been eliminated, and mortality from cholera and other related diseases has decreased. But episodes of cholera continue to recur, and the incidence of tuberculosis is not insignificant. The situation in regard to public sanitation, preventive healthcare, control of communicable diseases and health education needs to be improved. In addition to the diseases of poverty and malnutrition, non-communicable diseases related to urbanization, such as diabetes mellitus, hypertension, cardiovascular diseases and cancer is a cause of concern. Road traffic accidents, geriatric problems and complications of autoimmune deficiency syndrome (AIDS) are also on the increase.

Though hospitals, dispensaries, public health centers and other medical facilities are present, they are not sufficient to cater to the growing needs of India's substantial population. Rural access to quality medical service has to be improved. The inadequate manpower of doctors in public sector hospitals is also a concern for health authorities. Furthermore, the infrastructure required in the hospitals, like medicine, furniture and equipment, are not adequate to serve the population. Compounding the problem, government spending on healthcare services is not up to the World Health Organization (WHO) norms of gross domestic product in healthcare.

Though the public sector is not expanding its healthcare services, private, co-operative and

	1991	2002
Hospitals	112,000	153,000
Hospital beds	811,000	914,500
Registered medical practitioners	394,000	577,000
Registered nurses	340,200	805,800

Table 1: Growth of the Indian healthcare sector from 1991 to 2002

other non-profit organizations have started hospitals and are providing medical services to the public. Moreover, the Government of India is taking other steps to improve healthcare. For example, the Government has, from time to time, appointed various committees to address the pervasive problems in the healthcare sector. In addition, it has demonstrated a strong commitment to population control, including the implementation of family planning programs geared towards controlling the population.

### **The right to health and advances in healthcare protection**

The Indian Constitution has incorporated the responsibility of the state in ensuring basic nutrition, basic standard of living, public health, protection of workers, special provisions for disabled persons and other health standards, which were described under Articles 39, 41, 42 and 47 in the Directive Principles of state policy. Article 21 of the Constitution of India provides for the right to life and personal liberty and is a fundamental right. Keeping in tune with the universal declaration of human rights and various other developments in the Indian healthcare sector, the judiciary has included the right to health under Article 21. In accordance with the recognition of the fundamental right to health, the Indian Government adopted a national health policy targeted "health for all" by the year 2000. Although the country couldn't achieve all the benchmarks by the targeted date, the Government has set a revised date of 2015, by which time it hopes to meet the millennium development goals.

The judiciary, through the process of judicial activism, has transformed the Indian health scenario. The right to health is now a fundamental right; hospitals are included under the purview of the Consumer Protection Act, ensuring timely and emergency care for patients in all hospitals (the patients can approach the Consumer Forums to redress grievances); and actions are taken against cases of negligence. The legislature has also introduced acts like the Transplantation of Human Organs Act, Prenatal Diagnostic Techniques Act, Medical Termination of Pregnancy Act and others to improve healthcare. The media has also played an important role, by bringing the problems of the healthcare sector to the attention of Government authorities.

### **Insurance in the healthcare sector**

Most developed countries have a widespread insurance network in the healthcare sector. But, in India, the insurance industry is only now picking up. The percentage of the Indian population having health insurance policies is very low, and there are

very few companies offering insurance in the healthcare sector. Nonetheless, it is expected that insurance will play a major role in the Indian healthcare system in the near future.

### **Availability of information and impact of information technology in healthcare**

Consolidated data on the healthcare service is not available, and the mechanism of assimilation of data on the national level is not efficient. However, there are islands of excellence in some of the national institutes and a few other centers. The developments of information technology, such as a computerized hospital information system, are available in some of the centers. In addition, the Indian Space Research Organization (ISRO) has embarked on a telemedicine project, which has potential to provide specialist service to remote areas.

### **Health tourism**

India, the land of Ayurveda, has a wide variety of special treatments to offer. In addition, there are hospitals practicing modern medicine that provide quality service at an affordable cost. When compared to the expense of medical treatment in Western countries, India's facilities for treatment, natural beauty and tourist destinations across the country will make it a popular destination for people of all nationalities seeking healthcare.

### **Accreditation**

In the year 2006, the quality council of India, through the National Accreditation Board for Hospitals (NABH) has come out with hospital standards that are applicable to Indian hospitals. The likelihood of an insurance boom in the healthcare sector and the potential for health tourism are important reasons for accrediting the hospitals. Therefore, accreditation and quality health service will be the main agenda of hospitals in the years to come.

### **Conclusion**

India has made striking progress in health standards in the post-independence era. Still, many feel that the budgetary resources for the health sector should be increased. International developments in information technology need to be utilized at the national level in an attempt for health data documentation. The sustained efforts to control the country's population and the political will to march towards the millennium development goals in health will help India to make a significant impact in the international health scene. ■

Global references for this article are available at [editorial@icu-management.org](mailto:editorial@icu-management.org).

## Critical care in India



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The specialty of critical care medicine traces its history to the polio epidemic of the 1950s, when mortality was reduced by using simple ventilators to support patients' respiratory function. Since then, critical care has evolved from being just a designated area of the hospital to being a specialty that is not site-specific, offering expertise to several areas both in and out of the hospital. Conceptually, critical care also has to encompass broader concepts from prevention to palliative services.

### Evolution of critical care in India

The growth of quality healthcare over the past 50 years in India is evident in the fact that the average life span, which was only 21 in the pre-independence era, has now improved to 63 years — largely due to public health measures and the provision of quality acute care in hospitals. It is appropriate to note that India's primary focus, as a developing nation, has been to address common problems, including malnutrition and infections. Critical care, still considered "expensive care," often took a back seat to these more basic needs. However, the recent economic growth of the country has created a large pool of middle class Indians, who can afford the benefits of modern and specialized care, when needed. In India, critical care medicine, as practiced in the West, is still confined to large metropolitan areas.

Critical care in India started in the late 1960s, with the beginning of dedicated coronary care units in Mumbai and a few other large Indian cities. The first coronary care unit in India was started in 1968 at the King Edward Memorial Hospital, Bombay. This was followed by similar units, in some of the large, private hospitals of Bombay and other large cities of India. In the 1970s, Dr. Farokh E. Udhwadia, a pulmonologist, developed the first respiratory care units in the country in two hospitals in Mumbai — a community hospital and a private one. Among other achievements, these units opened the eyes of society to the need for critical care services.

As one might expect, the early intensive care units (ICUs) were primitive in technology, but had personnel with strong commitment to making a difference in patient care. The mid-1980s saw a significant improvement in the infrastructure and standard of care provided in intensive care units, thanks to the evolution of corporate hospitals with investors from within India and overseas. The first real advances in the field of critical care were brought about by consultants returning to India after completing training abroad, in the United Kingdom, the United States and Australia. The centers to which these consultants returned, including Mumbai, Pune and Chennai, remain centers of

academic creativity and administrative capability. These few, enthusiastic trained consultants came together in 1992 to discuss critical care on a common platform, and they formed the Indian Society of Critical Care Medicine (ISCCM). The society has now established itself very firmly as a representative body of critical care consultants in India, with over 2,500 members and 16 city branches.

### Diversity of healthcare services

It is not surprising that, in a country like India, which is vast and comprising more than a billion people, varied forms of healthcare are prevalent in different geographical areas.

#### Community Hospitals

Community hospitals are mostly run by the government and essentially result in minimal or no cost to the patients. Since critical care involves substantial technology and costs, there have been significant limitations to its growth as a specialty in such community hospitals.

#### Teaching Hospitals

There are currently about 200 medical colleges, or "teaching hospitals," in India, but only a small proportion (approximately 10-15%) of these have an adequately staffed ICU with appropriate infrastructure.

#### Tertiary Private Hospitals

Societies, trusts or companies usually manage tertiary private hospitals. Patients are levied a charge for these services. According to the current estimation, 85% of patients are self-paying, and others have third-party payers. ICUs in private, tertiary care hospitals are usually well equipped and provide critical care services on par with the rest of the world.

#### Small Hospitals and Nursing Homes

Finally, an interesting segment of healthcare facilities in India consists of small hospitals or nursing homes. Modestly equipped and managed mostly by medical professionals themselves, these facilities represent the healthcare solution for the vast majority of the middle and lower classes, and they contribute about 40% of available beds for the country. Patients also usually pay for the services

in these facilities. This segment acknowledges the need for and viability of critical care, and, currently, critical care facilities are on the upswing.

### **Critical care training & education**

Formal critical care training did not exist in India until recently. However, interested individuals pursued training abroad, some of whom returned to India. The formation of Indian Society of Critical Care Medicine has been a landmark in the history of critical care education in India. The one-year certificate course in critical care offered by the ISCCM since 1999 was India's first organized training activity in critical care medicine for doctors. The course, though not endorsed by the Medical Council of India, has evolved rapidly over the past few years and has gained recognition from institutions in India and overseas.

It is noteworthy that, right from the beginning, the focus of the ISCCM was to ensure recognition of critical care as a subspecialty for those with postgraduate qualification, and not just an added quali-

### **Challenges**

The current critical care scenario, though in some ways is encouraging, also has features that are cause for concern. For example, there are no laws or regulations framed either by the government or the local and national medical authorities that determine the standards or efficacy of a critical care unit or the qualifications and experience necessary for a physician to practice critical care. In addition, critical care is not well developed in rural India, where a significant proportion of our country's population lives. The economically weaker section of the Indian population depends on government hospitals, where major efforts are needed to upgrade the infrastructure to provide better quality care. Disturbingly, several smaller and inadequately equipped centers focus on advertising their ICUs, when in fact they are unable to offer comprehensive critical care to patients.

Trained nurses remain the cornerstone of multidisciplinary critical care. However, the lack of formal certification and the global attraction for monetary

**Critical care in India is at the  
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but there is still a long way to go.**

fication for those with a basic medical degree. Regular conferences, updates, continuing medical education programs and workshops have emerged, and postdoctoral training programs have been developed. In essence, critical care training for doctors appears to be assuming shape, but formal training for nurses and other support staff has not yet evolved meaningfully.

In addition to these training opportunities, scientific publications have begun to appear, and in spite of diverse problems and standards, meaningful specialty-related activities have begun. The Indian Journal of Critical Care Medicine (IJCCM) is currently the only scientific journal exclusively dedicated to critical care in India, although publications relating to intensive care do appear in other reputed Indian medical journals. The professional society has also taken the initiative to develop guidelines that are of value in the local setting and also promoting research to better understand the commonalities and differences between Indian and Western data. Finally, good quality, original work has now started emerging in India and is being accepted for publication by prestigious international journals.

gains leads to a shortage of experienced nurses. The concept of multidisciplinary care with a team comprised of nutrition specialists, physiotherapists, clinical pharmacists and social workers is still limited to large, tertiary care centers in private and teaching hospitals.

While the concept of the intensive care unit has gained widespread acceptance amongst medical professionals, hospital administrators and the general public, recognition of the need and role for qualified critical care specialists has lagged behind. The open-model ICU still remains the dominant model in India, although a few closed ICUs and transitional ICUs exist in the larger tertiary care hospitals in metropolitan cities.

### **Conclusion**

Critical care in India is at the crossroads of development. A beginning has been made, but there is still a long way to go. The field has its opportunities, threats and challenges in India. Some of these circumstances are similar to those faced by the Western world several years ago, but others are truly unique. ■

# ISCCM certificate course and critical care education in India



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## Introduction

Critical care is still a fledgling specialty in India, despite the fact that intensive care units (ICUs) have been in existence here for more than thirty years. Traditionally, critical care has been the preserve of anesthesiologists, as many of the skills required in critical care were part and parcel of anesthesiologists' postgraduate training. With the expansion of critical care's scope beyond perioperative management to include critically ill medical and surgical patients from all specialties, the skills and training of an anesthesiologist were no longer enough to grapple with the increasing complexity of intensive care management. At the same time, other specialists desiring to practice critical care did not possess an anesthesiologist's skills, which are inherent to the practice of critical care.

## Critical care education in India

In India, the initiative to start critical care education was taken by the Indian Society of Critical Care Medicine (ISCCM, [www.isccm.org](http://www.isccm.org)). Dr. Farhad Kapadia and others formed a committee to lay down guidelines for running a certificate course in critical care medicine. These guidelines included criteria for the recognition of critical care units and teachers to impart critical care training, the creation of a syllabus for critical care, entry criteria for trainees and an exit exam for certification at the end of training. Initially, only a few units in Mumbai and Pune were recognized for the certificate course. Over the last nine years, more than 25 units have been recognized for intensive care training, and every year, about 50 candidates appear for the certification exam.

The certificate course enables postgraduates in anesthesia, medicine and other specialties to get a feel for intensive care and either practice as critical care specialists in India or use their training to seek further educational and job opportunities abroad. Candidates are required to work for a year under the supervision of a recognized teacher at a recognized institute and acquire the basic competencies for intensive care practice. The training during this period involves bedside teaching; seminars; workshops in cardiopulmonary resuscitation (CPR), mechanical ventilation and hemodynamic monitoring; and critical care review courses. At the end of training, candidates appear for an exit exam, which includes written, practical and oral components.

Seven years ago, the National Board of Examinations, New Delhi, recognized the need for spe-

cialist training in intensive care and instituted a post-doctoral fellowship in critical care. Ten units from all over the country impart this training. Certification for the fellowship is attained through successful completion of an exit exam at the end of two years.

Apart from this, there is a DM in Intensive Care offered by the Ramachandra Medical College and Deemed University in Chennai, and there is a DM in Pulmonary and Critical Care Medicine offered by Post Graduate Institute, Chandigarh. Additionally, many private bodies and universities plan to offer specialist training in critical care in India. There is therefore an urgent need to create a common platform for training in intensive care in India, and the Medical Council of India and the National Board of Examinations must take the lead.

## The future

Currently, the Australian model for intensive care education, in which a Joint Faculty of Intensive Care Medicine (JFICM) regulates all aspects of intensive care training and certification, appears to be the best formulated, integrating the training required for the practice of intensive care in the most comprehensive manner. Under this model, candidates typically require about seven years (after undergraduate education) to complete training in critical care, after which they take an exit exam and are certified by the JFICM for practicing critical care. India can learn from this model.

The European Society of Intensive Care Medicine (ESICM) has recently completed a unique project, Competency-Based Training in Intensive Care Medicine in Europe (CoBaTrICE), which has used consensus techniques to define the competencies required of a specialist in intensive care medicine, linked these competencies to a syllabus and relevant educational resources and provided guidelines for the standardized assessment of competence in the workplace ([www.cobatrice.org](http://www.cobatrice.org)). The ISCCM has decided to introduce a two-year diploma course, which aims to use CoBaTrICE for training intensive care trainees. The ISCCM hopes to take the lead and transform the certificate course into an international, competency-based training program and, at the same time, work with the National Board of Examinations to create a national core curriculum on intensive care. Finally, with sufficient lobbying and advocacy, it may be possible to obtain the Medical Council of India's official recognition of critical care as a specialty. ■

# Antimicrobial resistance in Indian ICUs

Infections with resistant organisms have reached alarming proportions in Indian intensive care units (ICUs). Changes in the healthcare system are necessary to control the spread of antimicrobial resistance.

## Introduction: The problem

In order to fully understand the problem, it is essential for individual hospitals and intensive care units (ICUs) in India to track antimicrobial resistance patterns over time. Using overall hospital data or Western literature to guide antimicrobial therapy in an Indian ICU may be inappropriate. To date, however, there are no systematic, nationwide data on the extent and magnitude of antimicrobial resistance in Indian ICUs. Nonetheless, there are reports of an alarming proportion of infections with resistant organisms in ICU patients.

tobacter compared to 2002-2003 (12% vs. 9%). Using ceftazidime resistance as the screening criterion, 65% of the *Pseudomonas*, 68% of *E. coli* and 71% of *Klebsiella* may have been ESBL producers. Fifty percent of Gram-negative organisms were resistant to piperacillin-tazobactam. Methicillin-resistant *Staphylococcus aureus* (MRSA) constituted 62% of Gram-positive isolates, but only 8% of all isolates. Four isolates of vancomycin-resistant enterococci were seen for the first time in our ICU in 2005 (Myatra et al. 2006), and we have observed an increasing trend since.

### Community

- Widespread use of oral quinolones and cephalosporins
- Free availability of over-the-counter antibiotics
- Self-medication by patients
- Availability of cheap generics of variable potency and quality
- Spread of resistant organisms by crowding and poor sanitary conditions

### Healthcare System

- Decreased awareness of infection control policies
- Absence of national agency to survey and report on nosocomial infections
- Unregulated practices in small hospitals

### Hospitals

- Lack of hospital-wide infection control or antibiotic policies
- Extensive empirical use of cephalosporins in hospitals and ICUs
- Prolonged use of antimicrobial prophylaxis in surgical patients
- Failure to restrict privileges to prescribe major antibiotics

### ICUs

- Predominance of open ICUs
- Failure to implement or adhere to infection control protocols
- Prolonged use of broad-spectrum antibiotics
- Inadequate staffing, especially nurses

Table 1: Factors contributing to antimicrobial resistance

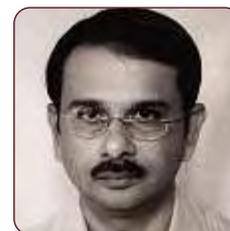
While susceptibility patterns may vary between regions and hospitals, all data indicate that *Pseudomonas* and extended spectrum beta-lactamase (ESBL)-producing enterobacteriaceae are the major resistant Gram-negative pathogens. In our ICU, in 2004-2005, *Pseudomonas aeruginosa*, *Klebsiella pneumoniae* and *E. coli* accounted for 25%, 14% and 14% of isolates, respectively. There was also a trend towards an increase in *Acine-*

toxin-producing *Acinetobacter baumannii* species. A particularly worrying feature is the increasing evidence of carbapenem resistance. Studies from North India (Gupta et al. 2006) and South India (Gladstone et al. 2005) indicate carbapenem resistance ranging from 12% to 37%, with resistance of *Pseudomonas* to meropenem as high as 54%. In our ICU, 41% of *Acinetobacter* species and 56% of *Pseudomonas aeruginosa* are resistant to meropenem, and 17% and 61%, respectively, to imipenem.

## Contributing factors

Antibiotic resistance in Indian ICUs results from an aggregate of

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# ICU versus ITU: Comparison of critical care services in India and the UK



Dr. Raja and colleague analyze the key differences in organization and delivery of critical care services in India and the United Kingdom.

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## Introduction

It has been well documented that intensive care unit (ICU) services may be heterogeneously organized within a single country, as in the United States (Angus 2006). Hence, it is not surprising that a comparison of intensive care delivery models in two countries, India and the United Kingdom (UK), is a study of contrasts. This article focuses on these differences, as well as advantages and potential limitations of each model.

## Intensive care coverage

Since healthcare delivery in the UK is administered through the National Health Service (NHS), a public-funded healthcare system, the distribution of intensive care services throughout the country is relatively homogenous. In India, there is wide disparity in the distribution of healthcare services (Purohit 2004). Marked contrast exists between state-run hospitals, offering near-free services with limited resources and infrastructure, and the private sector, offering 'state of the art' care to the patient segment with purchasing capacity. As intensive care is expensive care, the majority of Indian ICUs are concentrated in urban settings and pooled in the private sector.

The average bed capacity of ICUs in UK is six, ranging from four to 22 (Department of Health). The occupancy rate is about 80 to 90 percent. This puts pressure on ICU staff to ration beds or organize inter-hospital transfers. It has also resulted in the development of critical care networks linking a series of hospitals in a geographical region, to facilitate the sharing of beds and transfer of critically ill patients. Well established protocols, based on guidelines from professional bodies, and the availability of trained staff ensure that adequate standards are maintained during the transfer. In India, most units have a bed capacity of 20 or more, with a range of 14 to 80 beds, and average occupancy tends to be about 60 percent. Hence, there is no shortage of acute care beds, though patient affordability of long-term care might be a limiting factor in many circumstances. There are no formal bed-sharing nor inter-hospital transfer protocols, due to barriers imposed by the inherent heterogeneity of the healthcare system.

## ICU staffing and organization

In the UK, critical care services fall primarily under

the anesthetic directorate and are staffed by consultants with dual certification in both the anesthesia and intensive care specialties. UK units function as either semi-open or closed models. In the UK, the responsibilities of critical care staff extend outside the ICU to attend or offer informal advice in other acute care areas, such as the medical admission unit and accident and emergency unit. Many ICUs in India, in contrast, are now managed by a separate critical care department, are staffed by trained intensivists and employ semi-open organizational models. Indian critical care staff responsibilities rest within their unit and do not extend to other departments.

In the UK, ICUs tend to have a high ratio of nursing staff per patient. Nurses in the UK play a key role in clinical decision-making and take part in daily clinical rounds. They closely liaise with patients' family members, updating them about clinical progress and other relevant details. Also, UK units employ nurse-driven protocols in ventilatory management and weaning, feeding regimen, glycemic control, etc. India is experiencing an acute shortage of qualified nurses, which results in a lower nurse-to-patient ration in India than in the UK (Oberoi and Udgiri 2003). Many of the practices delegated to nurses in the UK are more often managed by a doctor in India. For example, Indian ICU doctors take primary responsibility for making clinical decisions and liaising with patients' families. Moreover, nurses (and patients' families, for that matter) are not as involved in end-of-life decisions as they are in the UK. In addition to taking the lead in decision-making, the attending physician in India also tends to take responsibility for routine practices, such as ventilatory management. On the other hand, there is no practical difference between the two countries in the presence of in-house doctors/trainees, physiotherapists, ancillary technicians and biomedical and clerical staff.

Support staff functions in the UK and India differ, as well. In the UK, the typical ICU has a bed manager to facilitate patient transfer, an ICU clinical pharmacist and a speech and language therapist doing daily rounds on tracheostomy patients. In addition, UK units include microbiology services in their daily ward rounds and discussions regarding diagnostic possibilities and appropriate antibiotic therapies. These functions are not always present

in Indian ICUs. On the other hand, while the availability of radiological services is a luxury in UK, there is never a major problem in ordering a bedside ultrasound, computed tomography, magnetic resonance imaging, echo cardiogram, or electroencephalogram in India.

In the UK, the role of critical care outreach services is well established and is an integral part of comprehensive critical care services. The delivery model is nurse-driven, and the role of a doctor is to step in when the team requests input in selected circumstances. The team works with an objective to avert ICU admissions by intervening early in clinical deterioration, following up on discharges from the unit and educating ward staff by sharing critical care skills. Along similar lines, the concept of rapid response teams, or medical emergency teams, is slowly coming into practice in India (Senthil Kumar et al. 2006). The key difference is, as these teams are ICU-based teams led by a doctor, the number of interventions done on-site is greater than those performed by UK outreach services.

### **Case mix and patient care**

In the UK, ICU admission is based on a classification of patient categories into four levels (Levels 0 to 3, with increasing number of organs requiring supportive care in each successive level). The final decision to admit the patient rests with the consultant on call in the unit. The case mix tends to consist of postoperative patients, as well as patients experiencing sepsis with multiorgan failure, trauma, toxidromes and respiratory failure. The majority of ICU patients in the UK are elderly. In India, no strict criteria for ICU admission exist,

and the decision to admit the patient is made by the primary physician. The ICU population in India is not that old, and the indications for admission, apart from the categories already mentioned in the UK context, include obstetric emergencies, tropical diseases like malaria, dengue with organ failure, immunocompromised patients, etc.

### **Other initiatives**

Clinical audit, to ensure adequate standards and quality of care, is an integral part of the clinical governance in UK. Unfortunately, this practice is not universal in Indian ICUs. On the other hand, while initiating clinical research is becoming a more and more difficult and time-consuming process in European ICUs (Truog et al. 2005), these limitations have not been observed yet in India, enabling clinical research to progress more easily there.

### **Conclusion**

To sum up, most of the differences observed can be traced to the healthcare delivery model prevailing in these two countries, i.e. the state-funded NHS in the UK, and a fee-for-service model (accounting for 82% of overall health expenditure and 4.2% of gross domestic product) in India. The different evolution of intensive care medicine in these two countries also results in differences. Intensive care in the UK is more traditional and well defined and dates back more than three decades, while in India, intensive care medicine is still a relatively new specialty and is rapidly expanding. Provision of intensive care in these two, very distinct settings will always require different approaches, but the experiences of each country may contribute to improvements in ICUs everywhere. ■

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without a doctor present, but again the introsseous route can be used by emergency personnel other than doctors, as can external pelvic compression devices in patients with hypovolemia due to suspected pelvic fractures.

Some special emergency services already do not use specialized doctors on-scene, like the emergency service in the Norwegian off-shore industry. Here, the search-and-rescue (SAR) helicopter service has functioned as a kind of air ambulance for more than 20 years. The medical crew composition is one specially trained anesthetic nurse and one paramedic. When necessary, they can contact doctors who are available on-line for diagnostic and

decision support at any time 24/365.

### **Conclusion**

Short on-scene time, combined with simple and safely performed life-saving techniques can be mastered by medical staff other than doctors, given proper training and effective organization. Sending specialized doctors out of the hospital, where many patients rely on their care, is a costly way of using physician expertise. Specialized doctors should be utilized for exerting tight on-line command and quality control of the EMS. Primary care physicians, on the other hand, must take part in the assessment of the emergency patient on-scene, especially in rural settings. ■

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sulbactam, etc.) and even ceftriaxone and vancomycin are aggressively marketed. Any physician can freely prescribe any class of antibiotic without notifying or being accountable to any health authority. In addition to large public and private hospitals, there are thousands of small, five- to 50-bed hospitals, which treat a significant proportion of patients who eventually reach large, tertiary ICUs. Thus, patients may arrive in the ICU with resistant organisms acquired in the community or in the small community hospitals. In the ICU, patients are at risk of developing nosocomial infections with resistant strains. Patients are commonly exposed to broad-spectrum antibiotics, and the nature of activities in the ICU facilitates cross-transmission of these resistant microbes.

### Countermeasures

Some measures to cope with resistant microbes have proven effective. Strict enforcement of hand-washing, implementation of infection control measures and elimination of the empirical use of

cephalosporins in our ICU has resulted in a decrease in MRSA isolates (12% vs. 8%) and a greatly increased sensitivity of Gram-negative isolates to ciprofloxacin. Pseudomonas resistance to ciprofloxacin reduced from 61% to 37%, and resistance to ceftazidime from 81% to 65% (Myatra et al. 2006). In an ICU in Chennai, curtailing cephalosporin use resulted in a reduction in ESBL-producing enterobacteriaceae from 45% to 20%. However, with increased use of carbapenems, metallo-beta-lactamase producing strains increased from 8% to 19% (Thodur et al. 2004).

### Conclusions

The problem of antimicrobial resistance in India appears to be similar to or perhaps even greater than that in Western countries. While we must take lessons from the West in coping with this problem, our unique healthcare system will need to be urgently reformed, and the necessary infrastructure for detection, reporting, monitoring, education and action will have to be put in place. ■

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run by streamlining processes, ensuring reliable and predictable outcomes and adding value in the customer relationship. Waiting for the return on investment, however, requires patience and endurance.

### Specific requirements for the ICU

More than in other healthcare areas, people working in intensive care units (ICUs) are extremely skilled and experienced within their domain. Formalization of their expertise through process descriptions, SOPs or quality manuals helps to make this knowledge transparent, understandable, re-usable and valuable for others (e.g. trainees, other specialties, patients and relatives).

A successful quality management system in the ICU has a bottom-up approach, as quality issues are often perceived where they first arise. Furthermore, process descriptions should use a breakdown structure to help chop complex problems into smaller chunks that can be dealt with one at a time and later be reassembled into the whole picture. This empowers ICU staff, which may be dedicated to contribute to a quality management system but would not otherwise know

where to start or where to go within a complex system.

As ICU processes change rapidly in the face of advancements in science and changes in patient status, ICU process descriptions and SOPs have to be living documents. All pertinent quality documents should be kept in a content management system, which may, for example, be available on the intranet. Fast, central updates by the responsible party are critical to keep the quality management system timely and accurate.

Department heads over physicians, nurses and support staff have to establish a delicate system of shared leadership, encouraging employee feedback and participation. Action and responsibility toward quality improvements must be delegated to the people at the point of service. Inversely, clinical management must co-coordinate, monitor and integrate all initiatives within the quality management system. Without total managerial dedication and involvement, the whole quality management system is doomed to fail. But, with the proper support and systems in place, an ICU is an ideal place to live up all aspects of total quality management. ■

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## 27<sup>th</sup> International Symposium of Intensive Care and Emergency Medicine

The 27<sup>th</sup> International Symposium of Intensive Care and Emergency Medicine (ISICEM) will be held at the Congress Center in Brussels from March 27 to 30, 2007, and we are looking forward to another exciting week of lectures, debate and discussion. The ISICEM is now the largest annual meeting of its kind, attracting almost 5,000 participants from around the world and including a faculty of some 200 international experts. At the meeting, participants are able to discover the latest pathophysiologic, diagnostic, technologic and therapeutic advances in their field. They also have the chance to meet other doctors from other units, hospitals and countries for informal "data-exchanges" over a cup of coffee or during lunch. Such conversations provide useful personal insight into how other doctors practice intensive care medicine and the different pressures and demands facing physicians worldwide. The underlying aim of the ISICEM is that each participant will take back to his or her intensive care unit (ICU) some new piece of knowledge or technique to share and implement at a local level, so that patient care can be optimized.

Below, I highlight just some of the many areas that will be covered during the 27<sup>th</sup> ISICEM. As always, sessions on sepsis will form an important part of the meeting. Sepsis affects more than one-third of ICU patients, and mortality rates for patients with severe sepsis and septic shock remain unacceptably high. The search, therefore, continues for strategies that will help improve outcomes. Results from recently completed studies, including those investigating the potential benefits of steroid therapy, assessing the value of strict glucose management, evaluating the effects of vasopressin administration and comparing various vasopressor agents in shock will be discussed. Further results from studies using drotrecogin alfa (activated) will also be presented, as the debate continues regarding the precise role of this drug in our ICUs. New approaches that show promise but are still at the experimental or early clinical phase of testing will also be introduced.

Acute respiratory failure is another common entity in ICU patients, but the "best" approach to

mechanical ventilation is still under discussion. Studies have not demonstrated a benefit of one mode of ventilation over another, but the titration of positive end-expiratory pressure (PEEP), optimal levels of tidal volume and methods of recruitment all need to be clarified. Non-invasive ventilation will also be further discussed as a useful option in certain groups of patients.

Importantly, the focus of intensive care is beginning to broaden to concentrate not only on acute, immediate resuscitation and ICU stay, but increasingly includes the longer-term outcomes and quality of life of patients who receive intensive care. Management of the patient while on the ICU is just one, small part of a much larger picture. The quality of life of post-ICU patients, determinants of long-term survival and the need for psychological support and ICU follow-up clinics will be covered in several sessions.

Finally, good management has an increasingly important role to play in today's ICU, particularly with the high costs of new therapies and interventions. ICU beds are a valuable and scarce resource, and difficult management decisions need to be made as to how best to allocate limited ICU resources. One approach to this is to try to "prevent" a patient's admission to an intensive care bed by using "medical emergency" or "ICU outreach" teams. These units, often comprised of an intensivist and an ICU-trained nurse, are called to the general floor when a patient fulfills specifically defined criteria, usually cardiorespiratory, which suggest they may be at risk of deterioration that could ultimately lead to a need for intensive care. By attending to such patients early and initiating appropriate therapies and management, outreach teams could potentially prevent an ICU admission. Several hospitals have now introduced these systems, and physicians from such units will discuss the benefits and limitations of this approach.

This is just a brief summary of some of the many and varied topics that will be covered in the 2007 ISICEM. There will be something of interest for everyone, and I look forward to seeing you there!



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## JANUARY 2007

16 Urgent Emergency Care Conference  
Telford, UK  
www.ukhcc.com/event/uec.html

## FEBRUARY 2007

5-9 15<sup>th</sup> Winter Symposium on Intensive Care Medicine  
Crans-Montana, Switzerland  
www.intensive.org

18-21 36<sup>th</sup> Critical Care Congress of the SCCM  
Orlando, USA  
www.sccm.org

24-25 1<sup>st</sup> Young Anaesthesiologist Conference  
Amsterdam, The Netherlands  
www.optionsglobal.com

## MARCH 2007

22-24 3<sup>rd</sup> World Congress Abdominal Compartment Syndrome  
(WCACS 2007)  
Antwerp, Belgium  
www.wcacs.org

27-30 27<sup>th</sup> Annual International Symposium on Intensive Care  
and Emergency Medicine (ISICEM)  
Brussels, Belgium  
www.intensive.org

## APRIL 2007

26-27 The Royal Oldham Hospital 4<sup>th</sup> Annual Critical Care Symposium  
Manchester, UK  
veerappan.chithambaram@pat.nhs.uk

## MAY 2007

22-24 15<sup>th</sup> World Congress on Disaster and Emergency Medicine  
Amsterdam, The Netherlands  
www.wcdem2007.org

## JUNE 2007

9-12 Euroanaesthesia  
Munich, Germany  
www.euroaenesthesia2007.com

## OCTOBER 2007

4-6 Emergency Medicine in the Developing World  
Cape Town, South Africa  
mcollin@curie.uct.ac.za

7-10 20<sup>th</sup> Annual Congress of the European Society of Intensive Care  
Medicine (ESICM)  
Berlin, Germany  
www.esicm.org

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2. Sulzer C. *Anesthesiology* 2001;95:1329-45  
3. Petter AH. *Anesth Analg* 2003;97:1743-50

[www.IntelligentVentilation.org](http://www.IntelligentVentilation.org), [www.hamilton-medical.com](http://www.hamilton-medical.com)