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## Ethics of Care

**Comparison charts: blood gas analysis**  
**Caring for patients' relatives**  
**Intensive care in France**

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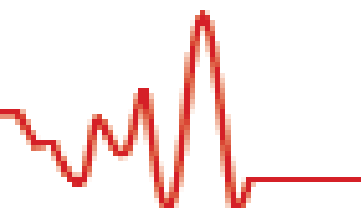
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*ICU Management is the official Management and Practice Journal of the International Symposium on Intensive Care and Emergency Medicine and was previously published as Hospital Critical Care*

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ULB

# Sharing knowledge in intensive care

Thank you to all of you who kindly supported the launch of *ICU Management*. Over 2000 copies of the first issue were circulated during the ESICM congress in Berlin last year, where the journal was warmly received by professionals from all disciplines related to intensive care.

*ICU Management* aims to disseminate information on the management, organization and implementation of evidence-based practices in intensive care. In particular in this issue we have focused on ethics, with thought-provoking logic from Professors Truog, Zamperetti, and Gomersall and a more hands-on approach in Professor Woodcock's article. Questions over conflicts between ethics and law, the opinions of medical professionals and patients, and representation of patients' wishes by relatives are all sensitive issues, difficult to handle in practice and requiring a multi-perspective understanding, and application of both the arts and the sciences. The implementation of ethical standards also comes into focus with the new European Union's Clinical Trials Directive. Professor Henry Silverman and our own European Affairs Editor, Helicia Herman, discuss the failings in this directive, the risk these pose to hinder research in Europe and what is being done to address the problem. Ethical practices further a field come into focus with Professor Truog's article on how the debate over medical futility has developed in North America. While Professor Gomersall explains the different premises on which the ethics of triage are based, Dr Albers and Professor Vahl from Germany, and Professor Van den Berghe from Belgium express their views on rescheduling elective surgery as a triage tool for intensive care services availability. Their different viewpoints originating from their own practices (a small specialized closed ICU and a large multidisciplinary surgical ICU respectively), are further explored by Professor Jukka Takala, who explains the solutions practiced in his own ICU in Switzerland.

Care of the relatives also comes under the spotlight with research on visiting hours and care of relatives. Professor Wilmer and his colleagues from Leuven explain their research into the needs of the relatives of dying patients, and how these findings can be implemented in practice through evidence-based recommendations. Professor Boles describes how open visiting hours in his own unit have provided a higher quality service to the relatives of patients during the end of life stage.

Further under our Management section, Professor Iapichino discusses a tool which may be useful to the management of your own ICUs. You might also like to read about the innovative purchasing strategy practiced at Haukeland University Hospital in Norway, which Hans Flaatten tells us about in his interview. This policy

has multiple benefits even above the obvious cost-saving ones.

With the high costs in intensive care and the need for careful research and strategizing in purchasing, we're introducing product comparison charts as a management tool. This issue, we are covering Blood Gas Analyzers. Drs Poelaert and Schupfer discuss organizational strategies to maintain and improve quality of care and cost containment with blood gas analyzers.

While research is needed to underpin evidence-based guidelines, databases provide an invaluable source of information on which to research and found good management and clinical practice, as Hans Flaatten points out with the national registry in Norway. Professor Reinhart and Dr Brunkhorst also provide an update on the PREVALENCE project in this issue. This is a national epidemiologic study in Germany for the estimation of the prevalence of sepsis, including assessment of treatments and related costs, and information on the current organization and structure of Intensive Care Medicine.

Only with sound theory, data collection and research can we implement evidence-based guidelines into the management, organization and practice of intensive care. Our aim with this journal is to contribute to the dissemination of information at all stages in this ongoing process, to all professionals in intensive care.

*Professor Jean-Louis Vincent*  
*Luk Haesebeyt*  
*Kirstie Edwards*  
*Christian Marolt*  
*Professor Jukka Takala*



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 Publisher, CEO of Euromedical Communications SA

# Management highlights from ISICEM

This year, the ISICEM is celebrating its 25th anniversary! Twenty-five years ago, in a university building, 200 doctors and 5 faculty members met for the very first ISICEM. The concept was that the meeting would promote intensive care medicine, then still a very young hospital specialty, that it would help doctors keep up to date with the latest clinical and research developments in the field, and that it would enable important contact between doctors from different hospitals and countries encouraging national and international discussions and collaborations.

On the surface much has changed: The ISICEM now welcomes almost 5000 participants and 200 faculty members; it meets at the vast Brussels Exhibition and Convention Centre to cater for the increased numbers; the overhead projector has been largely replaced by PC-run presentations;... But, the underlying concept and objectives remain unchanged - to bring together professionals from all corners of the globe to discuss and

with increasing numbers of patients and increasingly expensive technology and medication on the other. Many of the symposium sessions will impact indirectly on ICU organization and management, but here we will highlight a few with more direct implications. Current and future approaches to rationing, delivery of intensive care, staff training, and computerized data management systems are covered in sessions looking forward to the next 10 years of intensive care medicine. Effects of staffing levels on outcome, cost-effectiveness of ICU therapies, conflicts between costs and quality, strategies to improve quality of ICU care, ...all will be covered in various session formats at this year's ISICEM. Antibiotic resistance and nosocomial infections are a key concern for all involved in ICU patient care including those in ICU management, as these conditions are associated with considerable morbidity and mortality, with resultant increased ICU stays and costs. Several sessions address the issues surrounding antibiotic resistance, covering basic epidemiology through to optimal antibiotic regimes, which may reduce the development of antimicrobial resistance and hence associated morbidity and costs. Many nosocomial infections are preventable and continuing awareness and application of preventative measures is vital; this important subject will be well covered during the meeting. Outcome statistics are often used as benchmarks for quality of ICU care and improving both short- and long-term outcomes must be a key aim of every intensivist. Outcomes analysis is more complex than it may seem at first glance and a session of 10 lectures will explore some of the issues in various patient groups. ICU outreach teams may provide a means of reducing costs and improving care by enabling earlier diagnosis and management, by preventing unnecessary ICU admissions, and by facilitating ICU discharges. However, not everyone is convinced that this approach is as perfect as it sounds, and there is no evidence showing that outreach teams improve outcomes. This sets the background for one of many interesting pro-con debates to be held during the symposium.

These are just a few of the many subjects that will be covered, providing something of interest for all professionals working in intensive care.

Efficient management of ICUs is increasingly important as we try to balance financial limitations on one hand with increasing numbers of patients and increasingly expensive technology and medication on the other.

debate the latest in clinically-based research in the fields of intensive care and emergency medicine, in an environment that enables and encourages them to discuss their own practice with colleagues from other ICUs in their own and other countries. In this electronic age and with (generally) efficient and rapid travel, international distances have never been smaller, but huge differences still remain in clinical practice at national and international levels, and meetings such as the ISICEM, which encourage cultural and scientific exchange, provide an essential part of ongoing medical education.

This year's Silver Anniversary meeting will be preceded, as every year, by a closed Round Table with 30 or so leaders in intensive care medicine. The 2005 Round Table title is "My ICU in 2015" and participants will discuss how they see various aspects of intensive care medicine, from organization and management to technology and treatment, developing over the next 10 years. This theme will run through the main Symposium meeting with several sessions covering likely future developments in intensive care medicine. Efficient management of ICUs is increasingly important as we try to balance financial limitations on one hand



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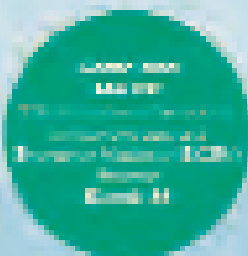


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## Research in Europe at stake

Concerns voiced before the EU Clinical Trials Directive (2001/20/EC) came into force are rising regarding the potential threat the Directive poses to non-commercial clinical trials.

### Introduction

In May 2001 the EU Directive 2001/20/EC implementing Good Clinical Practice (GCP) for clinical trials was published, requiring full translation into EU member states' national legislation by 01 May 2004. Concerns against the provisions of this directive were voiced before it came into force and groups such as the European Organisation for Research and Treatment of Cancer (EORTC) are still working hard to avoid the disappearance of non-commercial clinical trials. The aim of the Directive is to unify the regulation of clinical trials across the European Union, whether sponsored by charitable organisations, industry or universities. Administrative provisions governing all interventional clinical trials have been simplified and harmonised, by establishing a transparent procedure, and creating conditions conducive to the effective co-ordination of clinical trials in the European Union by the authorities concerned. No distinction is made between commercial and non-commercial clinical trials. The Directive intends to facilitate the internal market in medicinal products, while at the same time maintaining appropriate levels of protection for public health. However, the Directive poses a number of important legal and financial problems for academic research.

### Petition

Problems posed by the Directive are related to sponsorship, the manufacture of marketed drugs, fees for ethics committees and authorities, provision of free drugs, on-site monitoring and increased administration.

For example, the Directive defines a "sponsor" as an individual, company, institution or organisation, which takes responsibility for the initiation, management and/or financing of a clinical trial. This model seems to be based on the industry context, where a company taking an innovative compound through its development programme is self evidently the sponsor. Non commercial trials usually operate differently. The principal investigator, the employer (i.e. a university), a funding body

and a clinical host collectively take responsibility for various aspects of the trial.

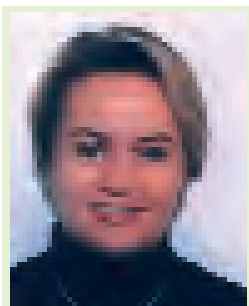
Out of concern for the future of academic and investigator led European research, a petition against the Directive was initially launched from a cancer platform, but gained momentum in cardiology, dermatology, and psychiatry. To date, more than 3000 people from Europe and beyond have raised their voices against the new regulations through this petition. In a next step, feedback will be collated from all the signatories on problems encountered due to the implementation of the Directive. In Ireland, for example, new clinical trial applications have reduced by 50% in the first five months since implementation. Examples will be listed in a new section on the website of the body organising the petition ([www.saveeuropeanresearch.org](http://www.saveeuropeanresearch.org)). The list will eventually be forwarded to the European Commission to invite a response.

### Outlook

EORTC undertook a snapshot review of all EORTC trials either recently closed, currently open or about to begin, and projected the consequences of the Directive on this set of 127 clinical trials. In the worst case, approximately 60% of all the academic drug trials would not have taken place.

At this stage, it is too late to repeal the Directive; however the "detailed notes for guidance" produced by the Commission, which address the practical implementation of the Directive, can be amended at any time and national authorities have some flexibility in implementation of the text.

The Directive moreover provides that all clinical trials must be conducted in accordance with GCP, for which the Commission has published a separate Directive laying down the standards. EORTC is currently discussing a text dedicated to specific modalities related to the new GCP Directive and the implementation of non commercial research with the European Commission.



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In accordance with the Clinical Trials Directive, the EU established EudraCT, a database of all interventional clinical trials of medicinal products in the Community, for which submission to the Ethics Committee and to the Competent Authority occurred on or after 1 May 2004. The database itself (available at the European Medicines Agency (EMA) website <http://www.emea.eu.int/>) is confidential and accessible only to the Competent Authorities of the Member States, the EMA and the Commission. However, a sponsor portal is available, which gives the sponsor access to the EudraCT application, in order to get a EudraCT number and access to supporting documentation.



# The European Union's **clinical trials directive**: the potential for inconsistent ethical practices in clinical trials

This article describes the lack of specification of the European Union's (EU) Clinical Trials Directive regarding proxy consent and safeguards for vulnerable subjects. This failing could lead to inconsistencies in the way member states implement ethical standards in recruitment for clinical trials.

## Introduction

The EU Clinical Trials Directive seeks to ensure consistency regarding the conduct of clinical trials involving new drugs in Europe (Directive 2001/20/EC). The Directive's goal is to provide an environment for conducting clinical research that protects research subjects without hampering the discovering of new essential medicines. The Member States had until May 2004 to incorporate the Directive into domestic legislation.

The Directive provides guidance regarding the protection of clinical trial subjects. It also gives further guidance for adult persons who are incapable of giving informed consent, because such incapacitated individuals represent a vulnerable class of subjects who "should be given special protection" (Directive 2001/20/EC). Specifically, the Directive discusses the identification of individuals who could provide proxy consent for vulnerable subjects, and additional safeguards to minimize the risk of harm and the potential exploitation of incapacitated subjects' inability to provide consent.

## The problem

Despite several commendable directives, the EU Directive lacks specification or complete guidance regarding proxy consent and essential safeguards for vulnerable subjects. Such a situation could lead to inconsistencies in the way member states implement ethical standards for the EU clinical trials directive. The potential for lack of harmonization in the ethical conduct of clinical trials could lead to confusion among sponsors, clinical research organizations, investigators, and others, thus creating an adverse perception of the EU as a desirable place in which to conduct clinical research.

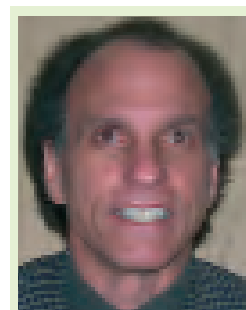
This article will describe the exact nature of the lack of specification of the EU Directive regarding the protection of vulnerable subjects enrolled in research. Such identification might help Member States incorporate more uniform guidelines in its subsequent regulations.

## EU Directive's guidance for vulnerable subjects

The EU Directive, consistent with previous ethics guidelines (National Bioethics Advisory Committee 1998; Tri-Council Policy Statement 1998; Council for Europe

1997; Council for International Organizations of Medical Sciences 2002) states that respect for persons entails that persons with diminished autonomy require special protection and such protection entails obtaining "appropriate" proxy consent for their participation in clinical trials. Accordingly, the Directive requires the written consent of a legally authorized individual and refers back to existing national law. The Directive recognizes that proxy consent might involve either a legal person (i.e. previously appointed through a legal process) or a natural person (i.e. a family member or close friend). Hence, the law of a Member State could give automatic legal authority to family members or close friends (i.e. without a prior legal process). Such a law would enable previously healthy persons, who become acutely and temporarily incapacitated to participate in clinical trials, e.g. patients with sepsis, strokes, trauma, or with a myocardial infarction.

The EU Directive does not specify the identity of natural persons. On one hand, such ambiguity allows individual Member States to adopt regulations informed by their different local conditions. On the other hand, such ambiguity could lead Member States to adopt approaches to proxy consent that differ greatly in the range of persons that could qualify as proxies. For example, the Austrian Drug Act does not allow family members to be automatically authorized to provide proxy consent for incapacitated individuals. The law in The Netherlands would empower only a legal representative, a spouse, or life companion to provide consent for incapacitated persons to participate in research. This list would exclude many persons who are unmarried, divorced, or widowed and without a life companion from participating in research. Such individuals might have parents or adult children who might be ethically appropriate proxies. In contrast, regulations in the United Kingdom and France are less restrictive and would even allow a physician to provide proxy consent for research participation. It is difficult to understand how such "third parties" can provide valid consent for incapacitated persons, as ethically appropriate proxy consent should either "represent the presumed will of the subject" (Directive 2001/20/EC) or know what would be in the best interests of the subject (Silverman et al. 2004).



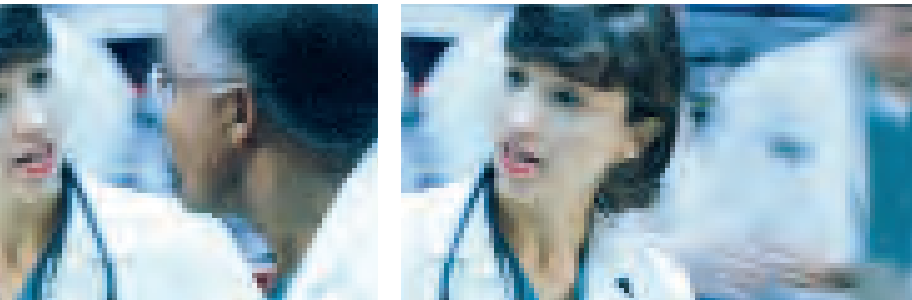
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Beyond the issue of proxy consent, the EU directive appropriately endorses other mechanisms to safeguard the rights and welfare of incapacitated individuals. These include the requirements for assent, dissent, the necessity requirement, and the subject-condition requirement. The necessity requirement would allow the participation of incapacitated subjects in clinical trials only if their enrolment is scientifically necessary. For example, the condition being studied causes incapacity in all persons, such as severe head trauma, or the research cannot be conducted in competent subjects with the same disorder. To enrol incapacitated subjects when it is not scientifically necessary raises the concern that such individuals are being targeted because of their easy availability or their inability to protect themselves. The subject condition requirement entails that the research must involve a condition from which the subject suffers.



The EU Directive, however, fails to mention safeguards that other guidelines have recommended for all research studies (National Bioethics Advisory Commission 1998). These include the requirement for investigators to outline a plan to assess the capacity of potential subjects when groups that might include incapacitated subjects are included in the study's recruitment plans, for example, for patients receiving mechanical ventilation or individuals with mild to moderate schizophrenia. For subjects previously enrolled in research via proxy consent, several research ethics guidelines recommend that there be a mechanism to obtain the informed consent of such subjects if and when they regain competency (Tri-Council Policy Statement 1998; Council for International Organizations of Medical Sciences 2002).

Finally, the EU Directive is silent regarding further safeguards for research involving non-therapeutic proce-

dures associated with more than minimal risk. Such safeguards could require the presence of an independent person to perform capacity assessments and the presence of an independent consent monitor, who could witness the informed consent process (Silverman et al. 2004). Finally, other ethics guidelines differ as to whether research that is greater than minimal risk should be prohibited (National Bioethics Advisory Committee 1998; Tri-Council Policy Statement 1998; Council for Europe 1997). The EU Directive is non-committal on this issue and could lead Member States to adopt varying guidelines for such research.

A final problematic issue involves research performed in the emergency setting. In such situations involving incapacitated individuals, there might be insufficient time to obtain consent from legally authorized individuals due to the narrow time window that usually exists for the administration of the investigational agent or intervention. The EU Directive fails to address this situation. Many fear that such silence will preclude potentially beneficial research in the emergency setting. As an alternative, many Member States have endorsed conditions under which such research may proceed with a waiver of informed consent (Silverman et al. 2004). However, such conditions differ greatly between Member States and could lead to further inconsistencies in the conduct of such research.

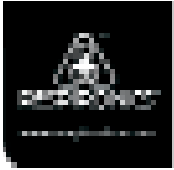
### Conclusion

The EU Directive's lack of specification and incomplete guidance regarding proxy consent and essential safeguards devolves too heavy a reliance on the diverse views of individual Member States as well as those of individual research ethics committees. Such a situation might lead to inadequate and inconsistent safeguards, thus making research ethically problematic (Silverman et al. 2001). A lack of clarity regarding research in the emergency setting might also lead to inconsistent and contradictory approaches. The potential for lack of harmonization in the ethical conduct of clinical trials among the Member States would lead to confusion among those who sponsor, oversee, and conduct research in the EU and will create an adverse perception of the EU as a desirable place in which to conduct clinical research.

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)  
Letters to the Editor in response to this article are also invited

## Press release

# The performance series™ one series fits all™



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**Dräger - New products, new concepts**

Dräger Medical released a portfolio of products and concepts at Medica 2004: a new concept for non-invasive critical care ventilation, the EvitaXL, a new disposable expiration valve for the Evita family of ventilators, the new D-Vapor desflurane vaporizer, Infinity® ChartAssist® VF2 and the Infinity® OneNet.

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**Gurit Medical Business/Medisize increases expertise and capacity in the medical sector**

Gurit Medical Business, a division of the Gurit-Heberlein Group, acquired Createchnic AG, based in Nürensdorf, Zurich, with effect from 1 November 2004. The Gurit-Heberlein Group specializes in clearly defined areas of the chemical and synthetics technology sector. The Health Care Division addresses two market segments: the dental sector and the medical and pharmaceutical industries, where the Group manufactures respiratory and disposable OEM products under clean-room conditions. Gurit is integrating Createchnic into the international Medisize Group, as part of Gurit Medical Business. Medisize is a specialist developer and manufacturer of airway management disposables, concentrating on the anaesthesia and critical care markets.

With around 100 employees, Createchnic manufactures high quality packaging, precision-dispensing and sealing systems, and disposable OEM products for some of the world's leading medical and pharmaceutical companies. The acquisition will put a wider range of production technologies and patented solutions at the disposal of Gurit Medical Business, while broadening its international customer base. It will also boost the Health Care Division's sales by approximately CHF 22 million annually.

**Maquet: Servo-i ventilator now supports non invasive ventilation**

SERVO-i ventilators provide moderated and reliable treatment for all patient groups while offering maximum ease of use. Depending on the requirements of the particular ICU, the software based technology is specifically configured for neonatal, paediatric and adult patient groups.

A new version of the SERVO-i now supports both NIV and suction procedures. NIV supports ventilation in the Pressure Control and Pressure Support modes. When using NIV, comfortable, effective continuous adaptive leakage compensation is made possible by a high sampling rate and adjustment during breathing, rather than after each breath. To increase patient comfort when introducing a mask, ventilation can be started either manually or by patient trigger, and disconnects are detected automatically. Much of the new functionality is also available in the SERVO-s series.

The SERVO-s has been created as a pre-configured,

**GE Healthcare introduces Engström respiratory carestation**

GE Healthcare, a unit of General Electric Company, launched the first critical care respiratory carestation, the Engström Carestation, at the 2004 ESICM Congress in Berlin. The Engström Carestation offers integration throughout the care process, from the ICU to the step-down unit, enabling clinicians to integrate ventilation with monitoring modules capable of measuring advanced parameters.

The advanced features include:

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- Plug-and-play modules providing advanced Datex-Ohmeda monitoring parameters;
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user friendly basic solution. Specially designed to cater for weaning ventilator patients off the machines, the SERVO-s includes non-invasive ventilation (NIV) and biphasic ventilation (BiVent functions). A recent software update for SERVO-s and SERVO-i simplifies treatment and sets new standards in terms of ventilation comfort and quality.

### **Radiometer launches the new ABL800 FLEX analyzer**

With the ABL800 FLEX blood gas analyzer, automated procedures ensure data accuracy and regulatory compliance, while two new supplementary services, FLEX-CARE and FLEXPAC maximize analyzer uptime and simplify management. ABL800 FLEX can be configured to measure any combination of pH, blood gas, electrolyte, oximetry and metabolite parameters with just 95 µL of blood. Immediate on-screen verification of correct patient information and accession numbers from HIS/LIS or RADIANCE (Radiometer's STAT analyzer data management system) ensures 100% data accuracy, a prerequisite for correct billing. Authorized users can access patient results from any RADIANCE-connected analyzer in the hospital directly on the ABL800 FLEX screen. With FLEXCARE, in addition to regular on site checks, Radiometer proactively ensures analyzer uptime by running system checks via a remote connection. With FLEXPAC, inventory management is reduced to a few order numbers, simplifying the ordering process and eliminating excess stock.

### **Research: cost of futility**

Dr Kanevetci and his colleagues at Akdeniz University Hospital in Turkey researched over a one year period the proportion, costs and prognosis of patients who were admitted to their ICU and who were not expected to survive according to their clinical experience. For the 145 patients who met the inclusion criteria, 83.4% died in the ICU, 3.4% died after ICU discharge, 7.6% were in a vegetative state, 4.8% in a severe neurological state and 0.7% in moderate neurological deficit when discharged from the hospital. Only one of the 145 patients included in the study had a moderate neurological deficit and survived. The total ICU stay was 2665 days and the mean daily ICU cost per patient  $534.5 \pm 157.5$  USD. During this period, an important percentage 33.1% of the ICU beds had been occupied by patients who were not expected to benefit from ICU treatment. The total ICU costs of those patients during the study period were 1,424,495 USD. An abstract of this study is reported in the Official Journal of the European Society of Intensive Care Medicine (2004).



### **Smiths - Emergency airway kit**

At Medica 2004 in Düsseldorf, Smiths Medical exhibited their Emergency Airway Kit for use by clinicians in civil and combat situations. Designed specifically for use in emergency situations, the Portex Cricothyroidotomy Kit (PCK) contains all the items required to establish emergency airway access. The kit is based on an innovative veress needle design that confirms entry in the trachea and indicates any subsequent contact with the posterior tracheal wall. Its 6mm bore Cricothyroidotomy tube enables spontaneous breathing and the Portex Soft Seal cuff secures the airway. The new device is supplied pre-assembled in compact robust packaging, making it ideal for inclusion in trauma bags.

### **\$925 million acquisition moves SMITHS into medical devices big league**

On the 6th December, the Smiths Group announced their agreement to acquire the privately-held US medical device company, Medex, Inc. Smiths will pay the current owners of Medex \$625m in cash for the company's equity, subject to any closing adjustment, with completion expected early in 2005. The acquisition is anticipated to give Smiths Medical a leading position in anaesthesia and safety devices, to increase Smiths Medical's sales by a third and profits by nearly a half, and provide the company with a strong platform for international expansion.

Medex products are highly complementary with the Smiths Medical range, selling to the same customer base in hospitals and other healthcare locations. Medex is a leading supplier of infusion equipment used in critical care, specialising in intravenous infusion catheters which prevent needle-stick injuries. These products are aligned in the market with the Smiths Needle-Pro range of safety devices. Medex pre-packaged trays of single-use products for catheterisation procedures are similar to Smiths' kits for anaesthesia applications. Medex also makes advanced syringe pumps which incorporate medication error detection, while Smiths is the leading supplier of ambulatory infusion pumps in the worldwide market.

## Medical **futility** in intensive care

What should be done when patients and families demand futile care? Recent advances in American law and ethics now provide a pathway for resolving these conflicts.

### Introduction

Many of the ethical and legal conundrums in intensive care medicine centre around patient rights, and two of the most difficult concern the rights of patients to refuse treatment, and the rights of patients to demand treatment. Europe and North America have taken very different approaches to these problems. In Europe, physicians have traditionally been empowered to make these decisions on behalf of the patients under their care. In contrast, the North American approach has been to cede much of this authority to patients and families.

Through the 1970s and 1980s, North America developed a strong ethical and legal consensus that gives patients a virtually unlimited right to refuse any medical treatment, even when physicians strongly believe the treatment is in the patient's best interest and should be administered. Only over the last 15 to 20 years has the debate moved on to the question of when, if ever, patients have a right to demand treatments that physicians believe to be futile. Since European standards seem to be moving away from physician paternalism and more toward patient-centred decision making, Europeans may have an interest in knowing how the debate over medical futility has developed in North American ethics and law. The issue can be examined from several different perspectives (Lantos 1994).

### Power

At its root, the futility debate is most fundamentally about power. Who has the power to say "no" when patients demand treatments that physicians regard as futile? Physicians argue that only they have the knowledge and expertise to make these decisions, whereas patients insist that these decisions are laden with values that fall outside of the authority of the medical profession, such as deciding what chance of success is "worth it," or how great a price is "too much."

### Trust

Closely related to issues of power are questions of trust. Futility judgments often concern life and death decisions. Why should patients and families trust physicians with these decisions? Indeed, a review of the futility cases that come to hospital ethics committees would show that many of them arise in situations where trust has broken down in the physician-patient relationship. Furthermore, patients can point to data indicating that physicians are poor predictors of survival from intensive care, and even worse at predicting the quality of life of

survivors (Frick et al. 2003). Not surprisingly, therefore, conflicts between physicians and patients over potentially futile life-sustaining treatments are often complicated by a lack of trust.

### Money

From another perspective, some insist that the futility debate is fuelled by a drive to save money. After all, if a patient with metastatic cancer insists on taking high dose Vitamin C in the absence of any evidence of effectiveness, few physicians would object, since the drug is cheap and easy to provide. On the other hand, if that patient insists upon treatment with high dose chemotherapy and a bone marrow transplant when there is no evidence of effectiveness, then physicians are likely to refuse, insisting that the treatment is futile and should not be provided.

Many physicians believe that a great deal of money could be saved by refusing to provide futile treatments. The data, however, indicate otherwise. Several articles, in both the adult and paediatric ICU literature, (Goh and Mok 2001; Halevy et al. 1996; Sachdeva et al. 1996) support the view that "The frequency of futile interventions appears to be low unless one is willing to accept a definition that includes patients who could survive for many months... this suggests that concepts of futility will not play a major role in cost containment" (Halevy et al. 1996).

### Integrity

On the basis of the above considerations, the futility debate could be described as a power-play by physicians to exert their authority over patients and families, in a context where patients do not trust physicians to make these decisions and where data indicate that physicians are not deserving of that trust. Furthermore, data show that allowing physicians to act on these decisions will not save a significant amount of money. Some have therefore concluded that the futility debate is dead, and that physicians should never be given the power to unilaterally refuse to provide treatments (Helft et al. 2000). This conclusion fails to account, however, for the fact that physicians are often motivated by the highest ideals in insisting that certain treatments not be provided. Certainly physicians must often inflict pain and suffering on patients as a necessary price for making them well. But when the treatments have little chance of benefiting the patient, persisting with invasive and aggressive treatments that can only harm the patient strikes many



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physicians as profoundly wrong and unethical. On this view, while futility determinations must be made cautiously and with a full realization of the ways that power, trust, and money may enter into the calculus of decision-making, there may be a small number of circumstances where such determinations are legitimate and indeed necessary to maintain standards of professional integrity.

### Diagnosing futility

If, as suggested above, futility determinations can sometimes be ethical, how should the diagnosis be made? The first suggestions called for diagnostic standards, such as claiming a treatment to be futile if it had failed in the last 100 attempts, or if it would only sustain survival in an ICU or a state of permanent unconsciousness (Schneiderman et al. 1990). Some hospitals actually adopted standards like these into policy, but unfortunately they found that such standards were exceedingly difficult to apply in actual cases, where the “messy” mix of circumstances, context, and details made definitive black-and-white conclusions highly suspect.

A breakthrough came in the late 1990s, when a variety of hospitals and organizations perceived that while it may be impossible to devise a workable “definition” of futility, it might be possible to create a “procedure” for evaluating specific situations that could be both fair to patients while also identifying cases where treatment was futile and should not be provided (Plows et al. 1999). All of these protocols share certain features, such as a process based upon deliberation by a multidisciplinary committee which includes community involvement, with formal opportunities for both the physicians and the patient or family to present their views about whether the treatment should be provided. Early experience with these hospital policies has been very favourable.

### Legislative developments

One problem with hospital based futility policies has been that they lack the force of law. On the basis of their encouraging early track record, however, several states have created legislation that recognizes a procedural approach to futility determinations. Baylor University recently published its experience with the law in Texas (Fine and Mayo 2003). In the 2 years after the law came into effect, 47 futility cases came before the ethics committee. In 43 of these cases, the committee affirmed the consensus of the clinical team that further treatment was futile and should not be provided. In these cases, 37 families acceded to the decision and agreed to withdrawal of treatment, whereas six families refused to accept the decision. Of these 6 families, 3 agreed within a few days of receiving the report, 2 patients died during the 10 day waiting period required by the law, and 1 died awaiting transfer to an alternate provider. Most importantly, none of the families went to court in an attempt to overturn the judgment of the committee.

As an interesting aside, the authors noted that even families who vigorously argued for maintenance of life sustaining treatments sometimes seemed relieved by the process. In other words, their data suggest that there may be some families who can never bring themselves to agree with a decision to limit life-sustaining treatment, but who will not object, if the decision is made for them. In the next several years, more states are likely to follow Texas and adopt futility legislation. While some might see this as a return to the traditional European approach of paternalistic physician decision-making, this would be an overly simplistic interpretation. The practice that is developing in North American ethics and law does recognize physician determinations of futility, but surrounds that determination with a process explicitly designed to respect and defend the rights of patients and families.

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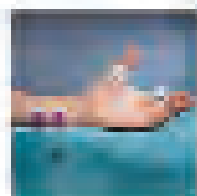
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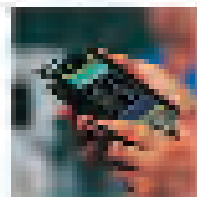
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# Managing a patient's refusal of vital supports: a personal position

Managing the request of an ICU patient to forgo intensive supports can be extremely difficult. Keeping different decision levels distinct, evaluating the patient's competence and building effective relationships among the patient, the patient's relatives and the healthcare team are essential steps.

## Introduction

Making end-of-life decisions is usually very difficult (Ardagh 2000; Cook et al. 1995; Prendergast et al. 1998; Ravenscroft 2000; Sprung et al. 1996; Vincent 1999) as it involves different decision levels (clinical, ethical, legal and relational). These levels must be kept distinct, avoiding any misleading confusion. A good practice is to clarify the clinical situation as much as possible, to decide which is the best possible approach, and finally to see how it can be best implemented from a legal point of view. Various aspects need to be taken into consideration.

- The clinical data must be established to a reasonable level of medical certainty. A decision based on incorrect clinical data cannot be morally or legally correct.
- Relationships are extremely important in intensive care. Somehow, especially in end-of-life situations, the way things are done is at least as important as what is specifically carried out. Good patient-relative-healthcare worker (HCW) relationships are essential to clarify patients' wishes and attitudes, and to help relatives to understand the situation and cope with it.
- Bioethics recognize some universal fundamentals, i.e. the value of moral principles, yet the interpretation of principles in each situation usually depends on local factors. Autonomy, for instance, can be intended as a personal (patient-oriented) definition of beneficence, so that it is somehow possible to limit it when it's contrary to some socially defined patient's interest (e.g. survival). Elsewhere, autonomy can mean self-creation, personal fulfilment, independent from beneficence; so the patient's wishes could be meaningful even if apparently irrational. Dignity can also have different meanings, ranging from full autonomy to duty of care to biological life. So, bioethics can be defined as a sort of culturally-mediated, community-based morality.
- Bioethics show what is good, whereas the law indicates what is legally permitted. Bioethics and law do not always concur. The hard part is keeping these two aspects distinct, without avoiding the "good" solution or sacrificing it either due to the absence of clear legal rules or for fear of legal consequences (Lemaire 2004; Meisel et al. 2000).
- Good terminology is mandatory. The term "vital support" can be misleading in terminal conditions, when actually the support is merely "agony prolonging". The forgoing of futile treatment should never depend on the

patient's refusal, but only on good medical practice. In this paper, only refusal of effectively useful intensive treatment will be considered.

## The patient's refusal of intensive support

Honouring ICU patients' requests to forgo effective intensive supports rarely happens without conflict (Franklin & Rosenbloom 2000; Franklin & Weil 1991; Grande et al. 1998; Lemaire 2004; Luce 2002; Veatch 2002). If a patient's request places his or her life directly at risk, HCW feel ill at ease, and sometimes try to overrule the directive, especially if the patient loses consciousness. Although understandable, this is illogical. If there were good reasons to accept a patient's decision when he or she was competent, this should also be honoured later, in the absence of new significant facts. Furthermore, when a patient loses consciousness, it may be too late for effective intervention, which is not only contrary to the principle of autonomy, but also more likely to be futile.

On the other hand, in rare and selected cases, it may be possible to overrule the patient's request and treat him or her when the proposed interventions are more likely to be effective, even if the patient does not accept them. Cases of patients treated in spite of their refusal of care are reported, and if the outcome is acceptable, such patients are usually grateful for having been cured (Grande et al. 1998; Vollmann et al. 2004). So, the real question is: can we accept letting people die just because they have refused treatment, if we can reasonably save them?

## The competence in ICU patients

ICUs are quite hostile environments and critically ill patients are not always in the best position to make sound decisions. We need to know what the patient actually wants. For a patient with inadequate competence and in the absence of reliable advance directives (AD), we need to guess. Families and HCW need to agree on a position that is both reasonable and likely to respect the patient's wishes. Nevertheless, it's still a matter of guessing rather than knowing. In a situation with unreliable knowledge of the patient's wishes, effective therapy and reasonably acceptable outcome, it is probably better to err on the safest side: i.e. by avoiding irreparable tragic consequences. If the therapy works, there is always time and space to forgo vital therapies,

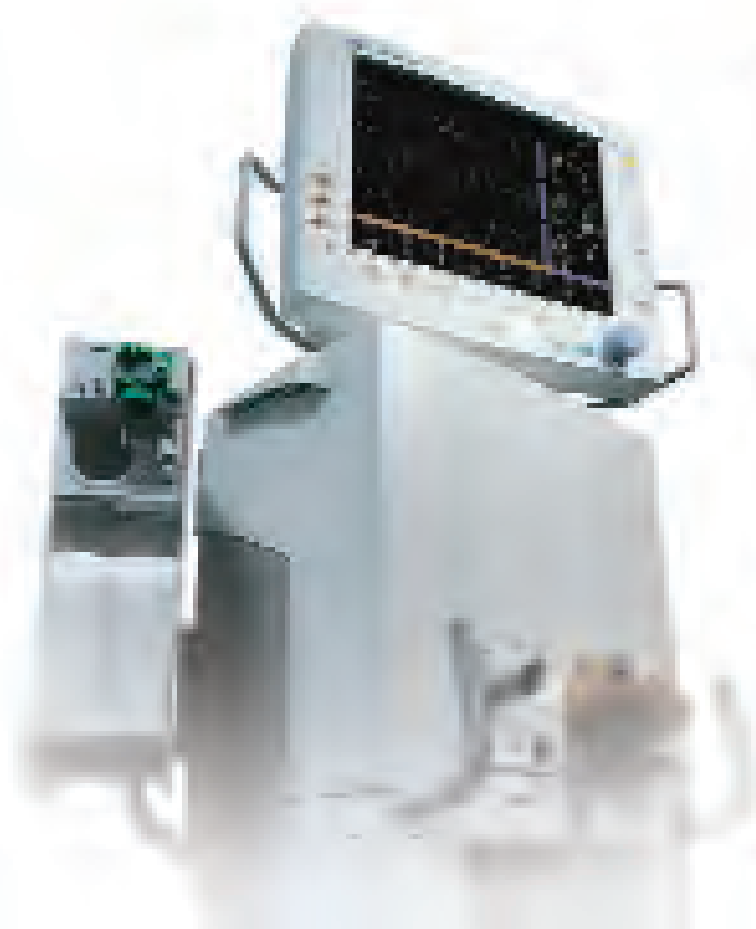


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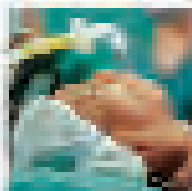
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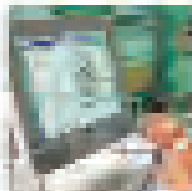
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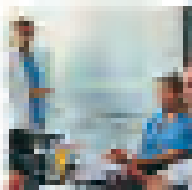
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if the patient chooses this, when he or she resumes competence. If the therapy does not work, then it can be forgone if it clearly turns out to be futile, and the patients can die in peace and dignity without physical and emotional suffering, albeit after an adequate therapeutic trial.



### Therapy and outcome, means and goals

The therapy is just a means; the goal is the outcome. If the informed patient reliably refuses the outcome, there is no reason to administer any therapy save for the compassionate ones. If the patient refuses the proposed therapy, but accepts the possible outcome, then our duty is to make effective therapy as minimally displeasing as possible. Credibility and patient's trust can be used to overcome a patient's fears. Also mild sedation can be used to help anxious patients. A vegetative state due to fear of needles (Franklin & Weil 1991) is a very poor outcome, in which the reverence of the patient's autonomy risks leading to a culture of deep loneliness; loneliness of patients left alone to die because of their fears, and loneliness of the HCW prevented from helping their patients.

### The meaning of medical care

The curing/caring activity has per se a content of morality. It is much more than a mere technical act. Tending a suffering person with the best possible efforts to help him or her to recover is a moral action. Certainly, its moral content is not absolute. It must be compared to the willingness of that person to be helped, to his or her views of life, morals and religious beliefs. Nevertheless, accepting every patient's decision, even when illogical and most probably contrary to his or her best interests and real wishes, may not always result in the best choice. A clinically sound and compassionately administered medical action should be considered a good and adequate approach until proven otherwise. The best proof is the patient's informed refusal of therapy. This is usually difficult to achieve in a clear way in ICU

patients, above all in emergency situations. Yet, decisions have to be made.

### A possible practical approach

- In practice, the consequence of refusal of an effective therapy should be weighed against the patient's acceptance of the predictable outcome. If the patient refuses the outcome, and such a decision appears in line with his or her views of life, morals and religious beliefs (so that the patient's decision can be considered as reliable), then this position should be respected until the end. This holds even if the probably acceptable outcome is only obtainable through means that the patient refuses, due to religious or well-grounded personal beliefs.
- On the contrary, if the consequence of refusal is clearly in contrast with the patient's views of life, morals and religious beliefs (as witnessed by the patient's relatives and friends), so that such a decision can be considered as unreliable, every effort should be undertaken to encourage acceptance of the therapy. Adequate sedation - if clinically indicated - can be a final, but acceptable resource in the patient's best interest.
- Deciding what to do is important, but how things are done can be even more relevant. Caring for the patient is crucial, whatever our decision. In particular, there are no clinical or moral reasons to deny sufficient analgesia and sedation to ICU patients, unless otherwise requested by the patients themselves.
- Also the relatives deserve attention. After an adequate involvement in the decision process, the patient's loved ones must be cared for during the terminal phase. Our work is not to return a dead body to the relatives, but to help them to accompany and participate with their loved one in the dying process. The needs of relatives must be identified and dealt with (Truog et al. 2001). This cannot be covered in a guideline, but can only develop from the careful presence of the health care team, in a "caring for the family while caring for the patient" approach.

### Conclusion

Excellence in intensive care can be measured by many indicators, including the quality of ICU death. A dignified ICU death can only happen through respect of patient's autonomy, adequate administration of comfort measures, involvement of relatives and fulfilment of their needs during the dying process. Verifying the patient's actual wishes, in order to effectively honour them, although probably the most difficult step in the whole process, is a fundamental one.

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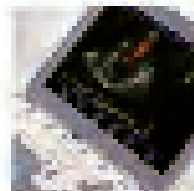
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# Patient **privacy** versus **teamwork** and surrogate **decision making**

Professor Woodcock provides thought-provoking case studies to help train intensivists on how to handle the sometimes complex legal and ethical issues affecting decisions over patient privacy.

Isobel is an unmarried 20-year old student. She was on her way to the Hospital to undergo termination of an unwanted pregnancy when a car driven by an alcohol-intoxicated woman left the road and struck her. She was admitted to Intensive Care for further treatment of a severe head injury. Her parents have arrived at the hospital, and wish to be told about her condition.

**Question:** You will of course explain the extent of Isobel's injuries and the purpose of treatment to her parents, but will you tell them about the pregnancy?

The European Society of Intensive Care Medicine's "PACT" educational program (ESICM, PACT Ethics Module, Woodcock and Sprung) introduces students to 'Patient Challenges' like this one as a way of drawing the student's attention to the solution of real-life problems. This method of education is particularly well suited to ethics and law, and in this article I will use the method to explore some inconsistencies within the concept of an incompetent adult patient's right to respect for her private and family life. When I put the above scenario to an international group of critical care doctors and nurses, I found general acceptance of the appropriateness of the following answer:

**Answer:** Your first duty is to your patient Isobel and you may only share confidential information about her to the extent that you judge she would wish to share that information in the circumstances. If she has not informed her parents of the pregnancy and her decision to terminate it, you should respect her privacy on this matter.

Now, however, the story becomes a little more complicated.

Isobel loses signs of brain stem function; now the decision is between withdrawal of assisted ventilation or organ donation or maintained cadaveric pregnancy.

**Question:** How and by whom is this choice to be made?

**Answer:** The circumstances are changed; we need to consider what Isobel would wish to happen in the event of her certain death. It may now be appropriate to disclose the existence of her pregnancy, and to hear family views on Isobel's values and likely wishes. Where there is unanimity of family view, and law allows, that view should be respected. Where there is dispute, negotiation and mediation can be tried, but the advice of a Court may ultimately be needed.

The international audience generally agreed that the changed situation shifted the balance of competing considerations so that Isobel's state of pregnancy ought to be disclosed to someone close to her. The interests of an unborn child are given different legal weight in different countries of the European Union, but few would doubt the interests of her fetus deserve consideration (Sheikh and Cusack 2004)

A sophisticated audience also sees a number of other interesting ethical conundrums in this developing scenario; why do reproductive matters seem to be so much more 'sensitive' than other biological functions? When brain function fails, do we think the situation is changed because Isobel has died or because she is dying or because she is alive but now disabled? What does this reveal about our attitude to the concept of brain death? Would we confirm brain death by apnoea testing if we know Isobel is carrying a viable pregnancy? Acknowledging that apnoea-associated acidosis and hypercarbia is extremely injurious, should we be more concerned about subjecting severely brain-injured patients to this test before we are convinced of the irreversibility of the patient's condition?

In the European context we turn now to consideration of Isobel's Convention Right expressed in Article 8 (European Convention on Human Rights web page.); "everyone has a right to respect for his or her private and family life, his home and his correspondence." "... except ... prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedom of others."

It is clear that Isobel's personal information can be legitimately shared among the treating professionals to the extent that it is necessary 'for the protection of health'. Teamwork is a fashionable concept, and one cannot imagine its proponents concluding anything other than that it benefits patients. The concept could, however, be used to justify disclosure of more information than is strictly necessary to more people than is strictly necessary. The limits of need to know will be different for the various health care disciplines, and according to the proximity of the team member to the delivery of care for Isobel. An interesting group in this context are students; disclosure of her private information to them cannot be said to be justified by the need to protect her health, and certainly not to protect her morals or anyone else's! What are the policies in your intensive care unit for information disclosure to students?



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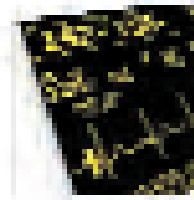
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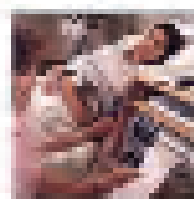
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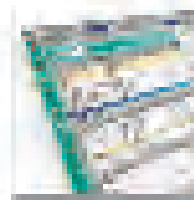
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# Giving life to Maternal-Infant Care



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Are your policies compatible with your patients' Convention Rights?

Private and family lives are not of course inseparable. We would expect Isobel's closer family members to be able to advise us on her expressed wishes and likely personal values, but we do not expect them to know all her most intimate affairs, and so we do not regard everything we learn about Isobel as disclosable. We do, however, look to family members when law or custom requires a surrogate decision maker. We must then share with them all the facts necessary to inform the decision. What of the father of Isobel's unborn child? Should we presume that her decision to terminate the pregnancy indicates her rejection of a relationship with him? Reflection on human relationships indicates that this is not always the case. But if we are to disclose information about Isobel to him, might his personal interest in the pregnancy be expected to colour any view he might then express on Isobel's likely choice or best interests? Let us ask another question about Isobel and her boyfriend.

Microbiology cultures reveal that Isobel has gonorrhoea.

**Question:** What factors would you take into account when deciding whether or not to inform Isobel's boyfriend that she has a venereal disease?

**Answer:** Weigh the public interest in the integrity of medical confidentiality against the public interest in protecting other people from a contagious disease. You will take into consideration the severity and treatability of the disease, and your proximity to or duty of care to the person at risk.

Disclosure of confidential information without the agreement of the patient can be justified in some other circumstances which are alluded to in Article 8. The prevention of disorder or crime is mentioned, though curiously the apprehension of perpetrators is not. At

Southampton, the Clinical Ethics Group have worked with our regional Police to develop policies and procedures to enable evidence to be collected from the person of a seriously injured patient who is unable to consent to, for example, the collection of body fluid specimens or forensic photography. As we saw above, the protection of health can include the health of others, but to outweigh the public interest in medical confidentiality the disease would have to be of substantial seriousness. Finally, there is consideration of the rights and freedoms of others. We finish with some general questions, unrelated to our friend Isobel, for you to contemplate. I do not provide answers!

**Question:** What factors would you take into account when deciding whether or not to inform the authorities that your patient confided with you that he had killed his wife before taking a potentially lethal overdose?

**Question:** What factors would you take into account when deciding whether or not to disclose a patient's verbal threat to inflict harm on a named person?

This paper is based on a lecture given at the European Society of Intensive Care Medicine's Annual Congress in Berlin, October 2004.



References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)



# Rationing and triage of admissions to intensive care

This article discusses the ethical basis of triage, current data related to triage and makes a plea for a consensus on definitions.

Refusal of admission to patients referred for Intensive Care is common (Azoulay et al. 2001; Frisho-Lima et al. 1994; Joynt et al. 2001; Metcalfe et al. 1997; Sprung et al. 1999) and occurs for a number of reasons. These include triage, futility and patient preference. Despite the tautology it is important to emphasize that refusal of admission and triage are not synonymous as this misunderstanding causes considerable confusion. Triage is defined as "the action of sorting according to priority". Inherent in the process is the fact that interventions that provide benefit will be denied to at least some people who could benefit from them.

The ethical principles underlying the practice of Western medicine are beneficence, non-maleficence, veracity, distributive justice and autonomy. Autonomy must inevitably be balanced against the principle of distributive justice and where one patient's autonomy will directly affect another's, as in triage, distributive justice must take precedence. This has important implications for the triage process: patient's opinions are of little relevance in the prioritizing process itself. If a patient receives a high enough priority to warrant admission to ICU then his right to autonomy clearly gives him the right to refuse admission. If, however, he has a low priority for admission his wish to be admitted should not significantly increase that priority: a system of admitting those who make the loudest demands is clearly not just.

In contrast, patient autonomy is of central importance in the concept of futility. It is important to note that treatments not patients are futile. A treatment that is futile is one that has no significant chance of achieving a specified target. It is for the patient to choose what constitutes an acceptable target (Youngner 1996). Thus from an ethical standpoint, refusal on the basis of triage and refusal on the basis of futility are distinct processes.

In order to fulfil the principles of beneficence and non-maleficence any triage system should aim to maximize the good and minimize the harm to society. It follows that those patients most likely to benefit from Intensive Care should receive the highest priority for admission on the basis that this will maximize the sum benefit. Certainly the guidelines from both the Society of Critical Care Medicine and the American Thoracic Society emphasize the central role of likely benefit in triage

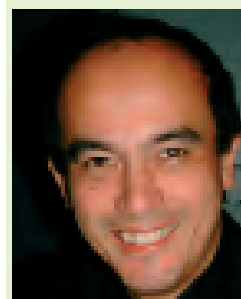
decisions (ATS Bioethics Task Force 1997; Task Force of the American College of Critical Care Medicine 1999).

What then is benefit, in the context of triage? Benefit should be considered in many dimensions, including quality of life and consequences for the family, but survival benefit is the most simple conceptually and is probably the most relevant to Intensive Care. When looked at retrospectively, it is clear that patients who die despite Intensive Care derived no survival benefit, while those who survive may have derived benefit (obviously some of these patients may have survived anyway). This retrospective approach is, however, of no value in the context of triage where one has to make a prediction of likely benefit. In this setting benefit is the predicted increment in probability of survival resulting from Intensive Care. In order to maximize beneficence in societal terms it is also necessary to consider duration of survival. Simplistically it is better to produce an ICU survivor that lives for 10 years than one that lives for 10 days.

Can we estimate benefit, even for a relatively simple dimension such as survival? What little data there are suggest that we cannot estimate likely benefit with any reasonable degree of accuracy (Ramsay et al. 2001): a finding that is not surprising given the paucity of data to help us predict the outcome of critically ill patients who are refused admission to ICU.

The other part of the equation, that has not been widely addressed, is the issue of resource consumption or cost. Again in simple terms, if the cost per additional survivor is low, then it should be possible to produce more survivors with a fixed resource.

So much for the theory; what happens in real life? Unfortunately the data related to the process of triage are limited. Sprung et al. (1999) studied 92 patients who were refused ICU admission (of whom 31 were subsequently admitted). Independent predictors of refusal of admission included diagnosis, age, operative status and a full ICU. Severity of illness was not independently associated with refusal. This, however, is likely to reflect the nature of logistic regression analysis and the likely relationship between severity of illness and probability of admission or refusal. This relationship is likely to be



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complex with a low probability of admission of patients with a low or very high severity of illness and a high probability of admission for patients with a moderate severity of illness. As a result logistic regression analysis may be misleading.

Certainly, Joynt et al. (2001) found that in 624 patients referred for emergency admission to ICU, the proportion of patients admitted was lowest in those with the lowest and highest severity of illness. In this study refusal of admission on the basis of triage was independently associated with severity of illness (as well as age and diagnostic group). It is noteworthy that this part of the study specifically excluded patients that were considered too well for ICU admission and patients for whom ICU admission was considered futile, thus excluding many patients at the two extremes of severity of illness and avoiding the statistical difficulties of Sprung et al.'s (1999) study.

Azoulay et al. (2001) studied 1,292 patients referred for admission to 26 ICUs, 283 of whom were refused admission. Factors independently associated with admission were age, chronic health and certain diagnoses. A median of four out of twenty recommendations for triage were observed. Whether this reflects inappropriate practice or inappropriate recommendations is not clear. Certainly some of the recommendations would not be appropriate to the process of triage as defined in this article.

Despite the central role that perceived benefit should have in triage, none of the above mentioned authors examined the relationship between perceived benefit and the decision to admit or refuse the patients.

The recurrent finding that age is an independent factor in the decision to admit or refuse a patient may be inter-

preted by some as evidence of ageism. This view, however, does not take into account the need to maximize benefit to society as a whole. In this context it is entirely appropriate to select patients who are likely to survive longer and, all other things being equal, the younger patients can be expected to survive longer.

Sprung et al.'s (1999) finding that a full ICU is a predictor of a decision to refuse admission to a patient deserves comment as it illustrates one of the difficulties in interpreting research into this area. At first sight the finding may seem obvious: when the ICU is full, patients cannot be admitted and no decision is necessary. This view, however, is based on an interpretation of "full" as being physically full with no patients who can be transferred out the ICU. Careful reading of Sprung et al.'s paper reveals that this was not the definition of "full" as patients continued to be admitted even when the ICU was "full".

What then is the way forward? An agreement on terminology would be a useful initial step. We suggest a definition of "triage" that matches the dictionary definition would be the most appropriate allowing non specialists in the area to easily comprehend its meaning. Given the different ethical basis for the two processes we suggest that refusal on the basis of triage is separated from refusal on the basis of futility or patient preference. We need more data to tell us what happens to the patients we refuse to admit and data to indicate factors related to outcome in this group. Combined with data and our experience of which patients are likely to survive Intensive Care, this will allow us to make a more accurate estimate of likely benefit. To address the cost issue, a study of factors present at the time of assessment, which are related to duration of stay, would be an initial step in allowing us to estimate likely costs.

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)



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# German competence network for the study of severe sepsis and septic shock (SepNet)

Drs Brunkhorst and Reinhart provide an update on the SepNet infrastructure and two scientific projects, which it supports, VISEP and PREVALENCE.

## SepNet

Faced with therapeutic stand-still and limited results of former trials in the field of sepsis, the major objective of SepNet was to establish an efficient infrastructure for sepsis research in Germany and to develop and initiate independent, innovative, internationally competitive, prospective clinical trials. Due to the limited funding awarded, the goals of SepNet are restricted to the establishment of the network structure with the following central facilities:

1. 23 regional study centres throughout Germany for the recruitment of patients for clinical trials within the network;
2. a SepNet office for all management and steering issues;
3. a Centre for Study, Coordination, Biometry and Telematics (CSCBT) to provide professional assistance for the planning, conduct and analysis of scientific projects and to provide an appropriate telematic infrastructure (remote data entry, communication, data management);
4. a central sample bank for serum, plasma and DNA samples of septic patients as a basis for future research projects.

Scientific projects funded by the German Ministry of Education and Research (BMBF) and by additional third-party support from the industry include:

- a) A randomized controlled interventional multi-centre trial to investigate the role of colloids vs. cristalloids for Volume substitution and the role of conventional vs. intensive Insulin therapy in the treatment of severe SEPs and septic shock ("VISEP-Study").
- b) A national epidemiologic study for the estimation of the prevalence of sepsis including assessment of treatment habits and related costs, and information on the current organization and structure of Intensive Care Medicine in a representative sample of German ICUs ("PREVALENCE Study").

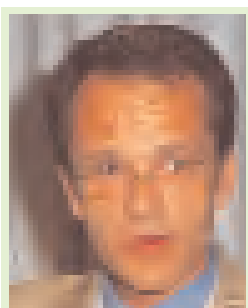
## VISEP

The VISEP trial was bifactorially designed to prospectively assess the choice of fluid resuscitation (hydroxyethylstarch 10% vs. lactated Ringer solution) and the quality of blood glucose adjustment by insulin treatment (conventional vs. intensive insulin treatment) on the mortality of patients with severe sepsis or septic shock (sample size: 600 patients). The primary endpoints are a reduction in the mean SOFA-Score (1.2 points) and a

10% reduction in the 28 and 90 day mortality rate, respectively (adaptive two-phase study design). Secondary endpoints are the frequency of renal failure in patients treated with colloids, the reduction in the occurrence of critical illness polyneuropathy in patients treated with intensive insulin therapy, time to haemodynamic stabilization, ventilator-free days and length of stay in the ICU. In 2002, the protocol, the case report forms, the working instructions and the applications for the ethics committees were prepared. The protocol was discussed and modified in collaboration with all SepNet members during the following General Assemblies. Since the VISEP-study was not part of the BMBF funding, SepNet obtained industrial funding to undertake this trial. The start of the VISEP study (originally scheduled for January 2003) was delayed since the quality of whole blood glucose measurements was not consistent enough among SepNet centres to satisfy scientific and safety needs. A uniform methodology for blood glucose measurement at the bedside needed to be established in all regional SepNet centres. HemoCue® (HemoCue AB, Ängelholm, Sweden) was the only device to fulfil such criteria. A quality control system was established by the SepNet Office together with the central laboratory of the network. The results of this quality control system revealed a high quality device, comparable with daily routine results in the central laboratory. An IT-infrastructure (eResearch Network from eResearch Technologies) for the central data base, remote data entry and central data and quality management was implemented successfully. Completeness, plausibility and consistency of data is checked by automated procedures on a daily basis with generation of corresponding query reports, which are communicated electronically to the trial sites. First patient visits for the VISEP trial began on April 1, 2003. In July, 2003, an amendment to the protocol became necessary to change the procedure for the diagnosis of the critical illness polyneuropathy, which is a secondary study endpoint. Since the start of the study, 428 patients have been enrolled.

## Sample Bank

A centralized Sample Bank facility has been established. With the goal to guarantee optimal homogeneity of sample quality with respect to pre-analytical conditions and long-term storage, Standard Operating Procedures (SOPs) were created addressing all relevant steps of



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sampling, processing of primary samples, and sample transport. Dedicated order forms were provided for contributing centres linking sample ID (bar-code label on samples sent to Sample Bank and order form submitted to data collection centre) and patient ID (order form sent to data collection centre); patient data were coded with pseudonyms and a data trustee ensures confidentiality of patient data.

Ascertaining homogenous sample quality allowed focus on obtaining samples of pre-defined, well-controlled, and homogenous rather than optimized quality; to this end, emphasis was placed on minimizing pre-analytical steps and sample handling outside the central Sample Bank facility. Pre-defined quality assurance procedures were detailed to and discussed with staff of contributing centres during dedicated, regular study meetings. A special "lab package", containing order forms, primary and secondary sample containers and a return envelope for EDTA samples for DNA preparation, was provided for each individual patient to be included in the study. To minimize the risk of sample mix-up, bar-coded labels were provided to transfer sample ID to all secondary samples after centrifugation. Centrifuged serum samples were frozen at the site of the contributing centre and sent batch-wise to the central Sample Bank. Our quality management helped to ensure that a vast majority of samples were obtained following these procedures.

The application procedure for use of banked samples obtained through the study was set out prior to sample acquisition. Researchers both from within and outside the SepNet study can apply to the central study board of SepNet; following approval by the board, the central Sample Bank will provide sets of sample aliquots according to (approved) user specifications. To implement logistics and quality management procedures for sample retrieval, compilation of aliquot sets and shipping is, thus, another goal for the upcoming phase of the project.

### PREVALENCE study

Although a large number of epidemiological sepsis studies have been performed in Europe and the US in the past years, sound data for Germany is lacking so far. In the study "Prevalence of severe sepsis and septic shock in Intensive Care Units in Germany", a prospective observational cross-sectional study, the network gathered data from 454 randomly selected ICUs in 310 hospitals in Germany and screened 3,877

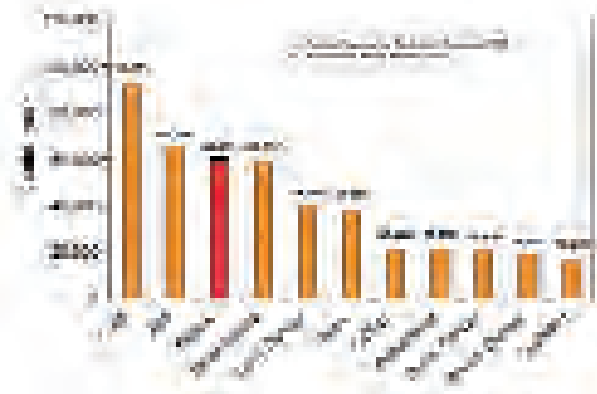


Figure 1  
Frequencies of causes  
of death in Germany

patients - according to the ACCP/SCCM Consensus Conference criteria - by local one-day visits of trained physicians from SepNet's 17 regional study centres. Visits were randomly distributed over a one year period (2003) to allow assessment of seasonal variations of sepsis prevalence. The ICU sample was taken from a registry of all German hospitals with ICUs (1380 hospitals with 2075 ICUs). Paediatric ICUs were not included. The study was completed in January 2004 and the data base closed on May 31. 7% of ICUs were situated in universities, 34% were university-affiliated and 53% in general hospitals. 56% of ICU directors were anaesthesiologists and 26% internists. An infection was microbiologically documented in 22% and diagnosed by clinical criteria alone in 12% of screened patients. Respiratory tract infections were most common (52%), followed by intra-abdominal (15%) and urogenital infections (7%). Gramnegative and grampositive infections were nearly equally distributed (33% vs 35%); in 16% a fungal infection was suspected. The prevalence of sepsis was 12%, infection without SIRS 7%, and severe sepsis/septic shock 11%. There were significant differences in the prevalence of severe sepsis/septic shock over one year with the highest prevalence in May/June 2003 (18%). The infection was ICU acquired in 37%, hospital acquired in 20% and community acquired in 35.5%. ICU mortality in patients with severe sepsis/septic shock was 47% and hospital mortality 54%. Based on these findings the incidence of severe sepsis/septic shock in German ICUs can be estimated to 75,000 cases per year (110 per 100,000 inhabitants), comparable with the incidence of acute myocardial infarction (143 per 100,000 inhabitants). With an estimated 60,000 deaths per year sepsis, severe sepsis and septic shock are the third most frequent cause of death in Germany after coronary artery disease and acute myocardial infarction (see figure 1).

For successful management of bacterial infections and sepsis

FEATURES

# Definitely PCT

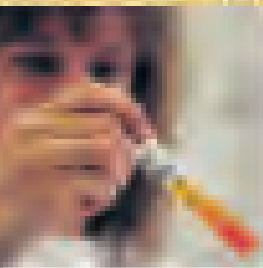
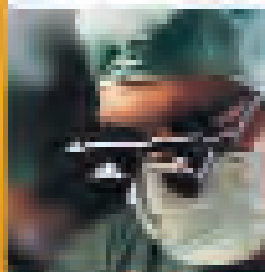


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- close monitoring of treatment and disease course

With an estimated 60,000 deaths per year sepsis, severe sepsis and septic shock are the third most frequent cause of death in Germany after coronary artery disease and acute myocardial infarction.

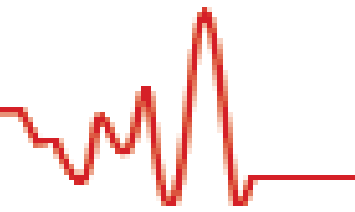
Incidence and mortality rate of severe sepsis and septic shock in German ICUs are higher than reported in recent studies. This may be due to the representative sample size, the more standardized diagnostic criteria and a lower inter-observer variability.

To increase the public awareness for sepsis, the German Sepsis Society (GSS, [www.sepsis-gesellschaft.de](http://www.sepsis-gesellschaft.de)) was founded on November 2001 among a group of SepNet members. The chair of the GSS (Prof. Reinhart) is the speaker of SepNet, and the board members are almost all SepNet members. The GSS fulfils different, but complementary tasks: whereas SepNet is a platform for clinical and basic research, the GSS is the scientific society for sepsis and responsible for all public relation and educational activities of SepNet. The GSS has defined recommendations for the diagnosis and treatment of severe sepsis and septic shock. These recommendations have been developed in accordance with the recommendations of the International Sepsis Forum (Intensive Care Med 2001; 27 Suppl 1: S1-134) and the Surviving Sepsis Campaign (Crit Care Med 2004; 32: 858-872). A Continuing Medical Education (CME) about sepsis was offered to all hospitals, which have been visited during the PREVALENCE Study and a promotion campaign has been started at national congresses and meetings. The organization of the CME is funded by the GSS and is free of charge for the attended hospital. For each presentation, SepNet and the GSS chose a speaker from the working group who is committed to the content of the prepared presentation. The GSS organizes a biannual international sepsis congress. The first congress "Sepsis and Multiorgan Dysfunction" was attended by 1100 visitors from 22 countries. Furthermore, the research prizes of the GSS, the Hugo-Schottmüller-prize and the Roger-Bone-prize have been awarded since 2002. The 2nd International Congress on "Sepsis and Multiorgan Dysfunction" will be held from Sept. 7 – 10, 2005 in Weimar.



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# What is the future of AMI treatment?

The future of heart attack treatment may depend upon the outcome of clinical trials such as ASSENT-4 PCI, which is evaluating the concept of early fibrinolysis followed by PCI in patients who cannot undergo primary PCI within the mandated time period.

The European Society of Cardiology guidelines for the treatment of ST segment elevation heart attack recommend that primary angioplasty/stenting be considered the preferred treatment when it can be performed by experienced practitioners, with experienced cath-lab teams, within 90 minutes of first medical contact (Van de Werf et al. 2003).

However, when we evaluate the current and future treatment of AMI, we see several considerations that will prevent primary percutaneous intervention (PPCI) from becoming a practical treatment option for most hospitals in most countries.

Relatively few hospitals, especially in Europe, are equipped with cath labs, and even fewer have 24-hour service. Very few can meet the mandated door-to-balloon time requirements. Even in hospitals equipped for round-the-clock procedures, the pressure of patients requiring interventions may be too great (especially as unstable angina/NSTEMI patients undergoing elective procedures are increasingly occupying the cath labs).

There is also the issue of quality: patients undergoing the procedure during 9 to 5 – normal working hours – are reported to have better outcomes than those treated during off-hours and/or weekends and holidays (Henriques et al. 2003; Saleem et al. 2004). Patient outcome may vary according to a centre's procedural volume, with higher volume centres producing better results than low-volume centres (Vakili et al. 2001; McGrath et al. 2000). There is also concern that patient outcome may be worse when intervention is performed at centres without on-site surgery facilities (possibly because these centres have a lower procedural volume) (Wennberg et al. 2004).

A possible solution, at least in theory, is to “timeshift” patients so that angioplasty need not be performed acutely. Such timeshifting could be accomplished by making prehospital thrombolysis (PHT) the initial strategy (in eligible patients), followed by either routine or ischemia-guided catheterisation.

Is this a viable option? Some dedicated interventionalists have argued that thrombolysis is a “second-best” treatment strategy, and all AMI patients should undergo

PPCI, even if it entails transfer from a community hospital to a tertiary facility (Andersen et al. 2003). However, in several studies, PHT alone has produced results comparable to those of PPCI (Bonnefoy et al. 2002). The evidence is particularly convincing where PHT has been integrated into the emergency department of hospitals, such as the SAMU emergency services of France.

Let us look at one study, CAPTIM, carried out by 27 SAMU hospitals experienced in PPCI and with a 24-hour team on call (Bonnefoy et al. 2002). This multi-centre trial enrolled 840 patients presenting within 6 hours, randomising them to either PHT with alteplase or to PPCI.

Thirty-day results were similar between the two strategies: there was no significant difference in the composite endpoint of death, nonfatal reinfarction, or nonfatal disabling stroke (alteplase 8.2%, primary angioplasty 6.2%). There was also no significant difference in the single endpoint of death at 30 days (alteplase 3.6%, PPCI 4.8%).

A follow-up report examined the effect of time to randomisation on outcome (Steg et al. 2003). Although time did not affect the primary composite endpoint of death, reinfarction, or disabling stroke, time did make a difference in the single endpoint of 30-day death. In patients whose time from symptom onset to randomisation was less than 2 hours, there was “a strong trend” ( $p=0.058$ ) towards a higher death rate in the PPCI arm (5.7%) than the prehospital lysis arm (2.2%).

The CAPTIM trialists concluded that time from symptom onset should be considered when choosing a reperfusion modality, and that “prehospital thrombolysis may be preferable to primary PCI for patients treated within the first 2 hours after symptom onset” (Bonnefoy et al. 2002).

Remarkably similar findings emerged from the real world of everyday practice in France, as documented in the USIC 2000 registry, in which trialists reported that “the 1-year outcome of patients treated with [PHT] compares favourably with that of patients treated with other modes of reperfusion therapy; this favourable trend persists after multivariate adjustment” (Danchin et al. 2004).

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**Table 1: In-hospital mortality and one-year survival in the USIC 2000 registry**

|                              | Thrombolysis | In-hospital thrombolysis | Primary PCI | No reperfusion therapy |
|------------------------------|--------------|--------------------------|-------------|------------------------|
| <b>In-hospital mortality</b> | 3.3%         | 8.0%                     | 6.7%        | 12.2%                  |
| <b>One-year survival</b>     | 94.0%        | 89.0%                    | 89.0%       | 79.0%                  |

(PCI, primary percutaneous coronary intervention)

USIC 2000 evaluated 1,922 AMI patients (Danchin et al. 2004). The median time from symptom onset to hospital admission was 3.6 hours for the PHT group, 3.5 hours for the in-hospital lysis group, 3.2 hours for the PPCI group, and 12 hours for those not receiving reperfusion therapy. The first three figures are similar, but there is a crucial difference: by the time they were admitted, the PHT group had already received the benefits of reperfusion therapy. This may explain the very low in-hospital mortality and high one-year survival rates of the PHT group (Table 1). Remarkably, none of the PHT patients admitted to hospital in ≤ 3.5 hours of symptom onset died in hospital, and their one-year survival was 99%.

Such relatively small trials and registry data suggest that PHT is at least as good as, and, in some situations or time periods, better than, PPCI. But whether PHT – or, indeed, early, in-hospital lysis – can or should be the first stage in a two-stage treatment program is an open question. Early trials – those performed in the 1980s, in which percutaneous intervention was performed during or immediately after full-dose lytic – suggested increased harm. However, much has changed since then, and the recent GRACIA trials were designed to re-examine the strategy using modern agents and techniques (Fernandez-Aviles et al. 2004; Fernandez-Aviles 2003). In GRACIA-1, (Fernandez-Aviles et al. 2004) the question addressed was not whether there should be post-lytic PCI, but when. This randomised, 500-patient, controlled, open study compared routine angiography within 6 to 24 hours of lytic administration plus follow-up intervention (if indicated) against a conservative post-lytic strategy of ischemia-guided angiography.

The primary endpoint, a composite of death, reinfarction, or revascularisation at one year, was reached by 9% of the routinely catheterised patients and 21% of patients in the conservatively treated arm, with a significant difference. According to the trialists, their results

suggest that early post-thrombolysis catheterisation and intervention is safe and might be preferable to an ischemia-guided approach because “it reduces the need for unplanned in-hospital revascularisation...” (Fernandez-Aviles et al. 2004).

In GRACIA-2, (Fernandez-Aviles 2003) which enrolled 212 patients presenting within 12 hours of symptom onset, trialists compared PPCI performed within 3 hours of randomisation with full-dose tenecteplase/enoxaparin administered immediately upon presentation, and followed by PCI within 3 to 12 hours. The combined tenecteplase/PCI strategy produced higher rates of ST-segment resolution six hours after randomisation. There was no difference between treatments in the primary composite endpoint of death, non-fatal infarction, and revascularisation, but, importantly, there was also no difference in bleeding complications. The investigators suggest that a strategy of early lysis followed by intervention is safe, feasible, and possibly more beneficial than PPCI alone.

Clearly, trials such as GRACIA are too small to warrant a change in clinical practice. However, a study that could alter the treatment paradigm is under way. ASSENT-4 PCI is comparing PPCI alone against PPCI preceded by a full dose of the thrombolytic tenecteplase. Patients are eligible if it is estimated that they will reach the cath lab/undergo start of the procedure more than 60 minutes and less than 3 hours after randomisation. Thus, the trial mimics the real world, in which patients delay seeking treatment, in which ambulances encounter heavy traffic, in which hospitals have no cath lab (or none available), and in which some patients undergo intervention so late that they fail to derive the utmost benefit that PPCI promises. It may be that the dual strategy of thrombolysis plus PCI will help resolve this perhaps otherwise irremediable problem. The ASSENT-4 PCI clinical trial results will be available in early 2006.

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)



# Ventilator pool management and standardization can lower the total cost of ventilation

New truly universal ventilators improve quality of care, productivity and lower the total cost of ventilation (TCV).

## Introduction

Over the last 20 years, there have been dramatic developments in intensive care ventilators. Due to new technologies and clinical evidence, advanced ventilation therapies are now commonly used in daily practice. Ventilators differ in terms of functionality, performance, and operating concepts. In most cases, devices are purchased from a departmental rather than a hospital-wide perspective, which results in a wide range of ventilators being used throughout the hospital.

The risks of inappropriate use are increased by different devices being used within a single department, staff moving from department to department, and ventilators being swapped when patients' acuity levels change. Most departments keep a "just-in-case" reserve of backup machines to be prepared for all eventualities. This reserve can represent a surplus of ventilators of up to approximately 20-30%. Training staff to use different ventilators is also very time consuming. Hospitals can therefore improve cost efficiency in both staff training and reserve ventilators by using one ventilator that offers a variety of ventilation modes.

Today, the industry is successfully using two approaches to lower capital employed while increasing productivity. The first is to standardize wherever possible; the second is to redesign management of the complete process of device usage.

Cross-department standardization of ventilators was previously impossible due to the varying medical requirements of different critical care wards. Different technologies required for neonatal, adult, and non-invasive ventilators restricted where specific devices could be used. Today's precision technology enables the design of truly universal ventilators, such as the Dräger Medical Evita XL, which incorporates all three technologies and provides the ability to fine-tune the system to the acuity of the patient. As a result, ventilators can be pooled for neonatal, paediatric and adult ICU wards, regardless of the medical specialty.

However, without appropriate process design, the cost saving capabilities of universal ventilators cannot be optimized. Bottom line impact can be measured by total cost of ventilation (TCV). TCV is influenced by the number of devices purchased and utilization of each device. Costs for training and technical service are driven by the number of different devices. TCV may include capital

## Total costs of ventilation

Capital costs (interest, depreciation)

Device transportation

Equipment room costs

Cleaning costs

Accessories and consumables

Technical service training

Device management

Stocking costs

costs (interest, depreciation), device transportation, equipment room costs, cleaning costs, accessories and consumables, training costs, and device management. If available, the cost for stocking items can also be included. Based on a recent project at a medium-sized German hospital, TCV can be as low as 70 euros per ventilation day, or as high as 200 euros. Taking the annual TCV and total ventilation hours into consideration, for a hospital with 10,000 ventilation days per year, such variation in daily costs could mean a difference of between 700,000 euros and 2 million euros in TCV per year.

The next step is to evaluate the number of ventilators used at the same time in different wards, as well as those in reserve or being cleaned or maintained. Plotting this data over time shows the pattern of base and peak usage. A process can now be designed to serve all departments from one pool of standard ventilators.

Depending on the hospital's infrastructure, goals for ventilator pooling management may include:

- Always enough ventilators available;
- Unused ventilators are managed (rented out, or leased);
- Ventilators cleaned after use;
- Ventilation accessories available (logistics, stock control);
- Preventive maintenance organized or performed;
- Usage documented;
- Users trained.

With the application of these two basic concepts, standardization and redesign of ventilator management, clinics implementing pool management can successfully lower their TCVs. The total number of ventilators and TCV will be reduced, while increasing device availability. Standardizing on a truly universal ventilator, such as the Dräger Medical Evita XL, and implementing and managing ventilator pools are key factors to success in ventilator management.

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# Impact

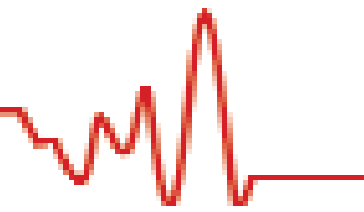
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# Does Bedside Blood Gas Analysis Reduce Costs in the ICU?

The design of studies to measure the costs of blood gas analysis in intensive care is difficult, with few studies reported to date. However, the authors advocate organizational strategies for quality of care maintenance/ improvement and cost containment: standardization of care, variable rather than fixed costs and internal price negotiations.

## Introduction

Providing care influences outcome favourably, but also has a dramatic impact on costs in an intensive care unit (ICU). Policymakers have concerns over cost containment and cost effectiveness, in particular for various routine activities in medicine (Sperry 1997; Vitez 1994). Attending physicians therefore need to take a close look at various routine tasks in medicine, such as daily laboratory testing and X-rays. Many institutions have implemented standards and guidelines, or so-called patient paths. Firm evidence to support the cost-effectiveness or even the clinical effectiveness of routine tasks in the critically ill patient care is scarce. Evidence-based medicine as an approach itself is not cost saving, but may generate scientific knowledge to apply new techniques and therapies.

The assessment of arterial or venous blood gases on a routine basis is a typical example where cost containment and cost-effectiveness could be implemented in a sensible manner. A clear understanding of economic analyses is one step towards insuring quality of care for patients.

Blood gas analysis is a typical example where the progression of technology renders this technique at least questionable concerning usefulness and cost effectiveness. Since the introduction and routine use of capnographs and oximeters in the ICU (Gottschalk et al. 1997; Shoemaker et al. 1996), it is evident that the frequency and need for arterial blood gas analyses has decreased considerably. Technology, however, is characterized by a continuous growth, with newer features becoming routinely available, such as blood lactate and glucose measurements. These additional options renew the appeal and interest in blood gas devices.

The best cost-containment strategy is to deliver the product at the highest acceptable quality with the lowest possible cost. Monitoring of the adequacy of oxygenation and ventilation is a cornerstone in the management of critical care medicine. In this respect, arterial blood gas monitoring is the golden standard for accurate and early detection of arterial hypoxaemia hypercarbia and changes in pH. Nevertheless, it requires invasive arterial pressure monitoring, which is not always available with ICU patients. In this overview, we focus on intermittent arterial and venous blood gas monitoring with respect to cost containment.

**Table 1: Definitions of various costs related to blood gas analysis**

| TERM                    | DEFINITION  |
|-------------------------|---|
| <b>Costs</b>            | Sacrifice measured as the price paid for the irreversible use of a resource (blood gas analyzer)  |
| <b>Direct costs</b>     | Cost of the material and labour used in production (includes cost of materials necessary to run the blood gas analyzer, disposables dispensing costs)   |
| <b>Indirect costs</b>   | Costs related to the consequences of an event for society or an individual, e.g. production loss  |
| <b>Intangible costs</b> | Expenses involving items that lack physical substance, e.g. goodwill  |
| <b>Fixed costs</b>      | Costs that remain the same regardless of the amount of goods or services provided (e.g. rent)   |
| <b>Marginal costs</b>   | Change in costs for producing one additional output   |
| <b>Semi fixed costs</b> | Expenses that remain unchanged only over a range of output, e.g. personnel costs in the operating theatre: they remain the same regardless of the number of cases in an operating session, but change with the number of cases performed outside normal hours (the over-runs and emergencies) |
| <b>Variable costs</b>   | Costs that change with the number of services (blood gas analyses) provided, e.g. number of doses of drug or anaesthetic disposables used   |

The difficulty is finding the balance between optimal financial expenditure to provide adequate care and restricting health care budgets. With respect to the latter, the threat is that budget control is so pronounced that an increase of the complication ratio is to be feared. Patients in an ICU, who undergo mechanical ventilator support for respiratory insufficiency, are evidently prone to cardiopulmonary complications, which could inherently prolong duration of mechanical ventilation, and therefore augment costs. In this respect, it seems logical to monitor ICU patients with arterial blood gases.

Definitions are required in order to gain an accurate idea of how to interpret cost containment and cost effectiveness. Cost definition, assessing economic outcome measures and managing care economically are important issues for today's medical practitioners (Sperry 1997). Table 1 presents some important definitions. The irreversible use of a resource implicates a price to be paid to use this facility. Direct costs comprise the use of materials and products to utilize the facility. In contrast, indirect costs are related to expenses related to an individual or/and the society. In delivering medical care it is necessary to set priorities and to define (or to estimate) the benefit to harm ratio relative to the cost. Another important point is that prices do not represent cost and benefit. Furthermore, costs are not synonymous with charges (Vitez 1994).

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Four types of analyses are commonly used:

- a) cost minimization;
- b) cost effectiveness;
- c) cost benefit and
- d) cost utility analyses.

**Cost minimisation**

Cost minimisation identifies the financial consequences of care, but assumes that outcomes after different treatment modalities are equivalent for a distinct disease. Such studies seek cost minimization and are usually useful in low cost situations when outcomes are not essential. From an economical point of view, we have fixed costs and variable costs for a blood gas analysis. In a typical setting of an ICU, the blood gas analysis is priced as a variable cost. Making costs variable is an efficient tool for cost control. If patient paths are implemented, the ICU physician is forced to negotiate these prices. We stress that the most efficient manner to minimise costs for blood gas analysis is variability of all laboratory costs in an ICU. Blood gas analysis costs are clearly related to a patient and his or her disease state.

In the emergency department, use of a pulse oximeter may allow significant reduction of unjustified blood gas analysis, which may permit a cost saving (Le Bourdelles et al. 1998). However, it should also be taken into account that modern blood gas analysis provides more information than optimal oxygenation alone.

**Cost effectiveness**

Cost-effectiveness analysis examines the net cost of care provided in correlation with outcome. This analysis technique considers life duration, quality of life, alternative treatments and incremental effectiveness. The nature and quality of evidence, the time horizon, the time value for money and all causes of mortality are also assessed. The key question is “Is it worth doing this (specific) intervention?” If the cost for blood gas analysis is truly a variable cost in a daily clinical setting, the decision can be taken, knowing the price of the analysis. Another approach is the standardization of care, in particular in using clinical pathways, where services and therapies for a typical patient with a diagnosis are outlined. By standardization of care, the final goal is not only reduction

of intravariance and intervariance of care, but also a reduction of the costs. Clinical pathways are supposed to have an effect on cost effectiveness and outcome (Imhoff 2000). To date, however, no study has shown rationing of blood gas analysis to have a beneficial effect. The importance is also minimal because of the low cost per blood gas analysis.

During the last 48h of life, blood gas analyses (Bamberger et al. 1996) are the most frequent requested analyses (20%) in surgical ICU patients, although the costs contribute only up to 5% of the total costs for these patients. The limitation of care in such situations is more a question of making a correct prognosis. The resuscitation status has a significant effect on the frequency with which these lab analyses are ordered.

Early goal directed therapy, based on central venous oxygen saturation monitoring, considerably improves the outcome of patients with severe sepsis or septic shock (Rivers et al. 2001). Although more blood gas analyses were undertaken, the knowledge from these assessments improved outcome significantly. With regard to the overall costs, these analyses were completely justifiable because of the low variable cost of blood gas analysis. Recently, this tool has been implemented into central venous catheters as an early warning system (Reinhart et al. 2004).

**Cost benefit**

Cost benefit analysis tries to quantify a benefit in monetary terms at a specific cost. The key question is “Are the achieved outcomes worth the cost?” Cost-benefit studies, with the classical meaning of these study types, are difficult to undertake in a critical care setting. To the best of our knowledge, no study is available to date discussing this item. Such studies are required in the context of the specific health care situation and system for each country. Implementation of guidelines, however, for blood gas analysis, increases efficiency of test utilisation without negatively affecting outcome (Pilon et al. 1997).

**Cost utility**

Typically all input costs are assessed with the generated output. The latter is measured in so-called utility units

**Table 2: Methodology of economic analysis applied to health care**

| Form of analysis   | MEASUREMENT  |                              | Examples of output measurements   |
|--|--------------|------------------------------|---|
|  | Input        | Output                       |   |
| <b>Cost minimisation</b><br>(outcomes are assumed to be equal) | Direct costs | No                           |   |
| <b>Cost benefit analysis</b>                                   | All costs    | Associated economic benefits | Money saved, earlier weaning from ventilator, earlier dismissing potential from ICU, return to work, production benefit |
| <b>Cost effectiveness analysis</b>                             | All costs    | Natural units                | Cases successfully treated, number of patients free of disease  |
| <b>Cost utility analysis</b>                                   | All costs    | Utility units                | Quality adjusted life-years, healthy years equivalents  |

(see table 2). As costs for blood gas analysis are only a small part of all fixed and variable costs for ICU care, such studies are actually redundant.

### Redesigning processes

The product in an ICU is also often difficult to define: are these cases, hospital days, interventions etc.? The definitions of costs and products are an important step towards analyzing and benchmarking productivity – an important cornerstone for cost containment. For this task, many scoring systems to estimate the severity of illness burden for an ICU are not validated. The duration of time spent in the lab- and therefore cost-intensive environments by the patient really determines the cost of care per event. Nevertheless resources are limited. The first step and simplest way to reduce resource consumption is to control resource allocation. One of the major components and rate limiting steps in managing critical care is gate keeping a triage. Using a highly sophisticated approach in treating patients, a patient's need for the high cost parts in the process chain of a surgical event can be optimized. Therefore, the efficient, effective processing of patients has the best opportunity to optimize cost of medical care.

- The use of clinical pathways is suggested as a tool for intelligent rationing in health care. Again it is important not only to focus on critical care, but also to put intensive care in the perspective of the entire continuum of care. Many decisions relevant to outcome, acuity and cost of the critically ill are made before the patient reaches the ICU. In this respect, arterial blood gas monitoring is a cornerstone in ICU management. Devices to measure blood gases and other features, such as blood glucose and lactate within the intensive care unit, often reduce the cost in several ways: less time to results before decision making, more rapid follow up and adaptation of both respiratory and metabolic management, additional determination of important parameters, such as blood glucose and lactate.

- Attention to organizational issues: significant reductions in mortality rates and improvements in resource efficiency have been observed when intensivists teams are actively involved in a closed ICU format and systemic triage (Rivers et al. 2001).

Redesigning protocols for routine lab investigations is associated with cost changes although without impact on quality of care in trauma patients (Jacobs et al. 2000).

Although few economic studies on blood gas analysis are available, a clear strategy is possible. To optimize costs, standardization of care and truly variable rather than fixed costs, together with internal price negotiations, are the most efficient strategies (fig. 1). However, blood gas



Figure 1  
Fixed and variable ICU costs

analysis costs should not be overstressed, as they are only a small part of the complete ICU care package.

### Conclusions

The ability to perform a reliable analysis of the cost-effectiveness of ICU care in general and for specific aspects of critical care, in particular, will greatly assist the process of determining how to focus limited resources appropriately in future (see table 3).

### Table 3: Links to health technology assessment websites

- [www.hta.nhsweb.nhs.uk/](http://www.hta.nhsweb.nhs.uk/)
- [www.sbu.se/www/index.asp](http://www.sbu.se/www/index.asp)
- [www.stakes.fi/finohta/e/](http://www.stakes.fi/finohta/e/)
- [www.inahta.org/inahta\\_web/index.asp](http://www.inahta.org/inahta_web/index.asp)

Although the clinical management of patients is an art rather than pure science, many aspects should be taken into account to produce critical care cost effectively: microbiology, pharmacodynamics, pharmacokinetics and economics. Any debate about cost in intensive care needs to assess the entire continuum of care. Therefore an increase in productivity with the aim of improving/maintaining quality should first be focused when cost containment initiatives are implemented, before we start rationing care. Attention to organizational issues of ICU care will result in improvement in the quality of care and a reduction of costs (Reinhart et al. 2004).

In addition, the design of relevant economic studies of the four types outlined above is difficult. These analyses need to handle moving targets, such as contract price changes, losses of patents etc. The study design needs to cope with questions of economics with a straight forward focus and hypothesis on either the health care system or a group of patients with a valid end point and clear cost model (Drummond and Jefferson 1996).

**“More is missed by not looking than by not knowing.”**

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)

# Blood Gas/pH Analyzers



## Introduction

ECRI is a totally independent non profit research agency designated as a Collaborating Centre of the World Health Organization (WHO). Such organizations are appointed to contribute to WHO's public health mission by providing specialized knowledge, expertise, and support in the health field to the WHO and its member nations.

Established as an Emergency Care Research Institute, ECRI opened its European Office in May 1995 with the goal of serving the particular needs of Europe and the UK. It is widely recognized as one of the world's leading independent organizations committed to advancing the quality of healthcare with over 240 employees globally.

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 more than 30 databases, publications, information services and technical assistance services set the standard for the healthcare community.

## The Healthcare Product Comparison System (HPCS)

Amongst its many products and services ECRI is pleased to provide readers of ICU Management with sample information about Blood Gas/pH Analyzers from its Healthcare Product Comparison System (HPCS) which contains over 280 reports.

The HPCS reports contain extensive information about the technology, its purpose, its principles of operation, stage of development and reported problems. In addition, this report contains worldwide suppliers of Blood Gas/pH Analyzer systems together with extensive model by model specifications for easy assessment and review. The Blood Gas/pH Analyzers Comparison Charts include ECRI's 'Recommended Specifications' (generic templates) which can be used for comparison and tendering purposes.

All of ECRI's products and services are available through the European Office, addressing the special requirements of Europe and the UK. Utilising some of the world's largest health related databases, help, support and guidance can be given to our European clients at a local level. The comparative tables overleaf, are extracted from ECRI's 2002 database. For full information, please refer to ECRI.

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## Footnotes for product comparisons on pages 37-39

- <sup>1</sup>These specifications are the opinions of ECRI's technology experts. ECRI assumes no liability for decisions made based on this data.
- <sup>2</sup>Models 840, 850 and 860 are upgradable to Models 845, 855 and 865, respectively. Upgrade includes the addition of an integral co-oximeter module. For more specific details on additional parameters with the upgrade, contact the manufacturer. <sup>3</sup>Also features a maintenance log. <sup>4</sup>Other ranges also available. Provided by ITC. <sup>5</sup>Also FiO<sub>2</sub>, code, room air, oxygen therapy mode, vent settings, mask/collar mode and patient modes. <sup>6</sup>Also 7.2 V, 2 A rechargeable battery or AC adapter (analyzer). <sup>7</sup>Models listed are currently marketed; specifications current as of September 2002. <sup>14</sup>Cartridges provided by ITC. <sup>15</sup>Other ranges also available. Provided by ITC. <sup>16</sup>Data management system provided by ITC. <sup>17</sup>ctBil (0 1.000 µg/mol/L), lactate (0-30.0 mmol/L), Hb; also FO<sub>2</sub>Hb, FHHb, FhbF, FCOHb, FMetHb, SO<sub>2</sub>. <sup>18</sup>(metabolite and oximetry modes only) 55 µg/L for pH, blood gases, oximetry; 95 µg/L for pH, blood gases, electrolytes, metabolites, and oximetry. <sup>19</sup>Also patient birth weight, gestational age, accession number, patient note, draw time, operator, physician, sample site. <sup>21</sup>PCO<sub>2</sub>(T), PO<sub>2</sub>(T), PAO<sub>2</sub>, PAO<sub>2</sub>(T), A-aDO<sub>2</sub>(T), and a/AO<sub>2</sub>(T) also available. <sup>22</sup>Also 33 patient and sample input fields.

## Healthcare Product Comparison System

|  |                               | ECRI RECOMMENDED SPECIFICATIONS <sup>1</sup>                      | BAYER   | BAYER  |
|--|-------------------------------|---|---|--|
|  |                               | CENTRAL/MAIN UNIT   | RAPIDLAB 860 <sup>2</sup>   | RAPIDPOINT 400; RAPIDPOINT 405 <sup>2</sup>  |
| <b>WHERE MARKETED</b>                              |                               |   | Worldwide   | Worldwide  |
| <b>FDA CLEARANCE</b>                               |                               |   | Yes   | Yes  |
| <b>CE MARK (MDD)</b>                               |                               |   | Yes   | Yes  |
| <b>TESTS AVAILABLE</b>                             |                               |   |   |  |
| - MEASURED (RANGE)                                 | BP, mm Hg                     | Preferred   | 400-825   | 523-800  |
|  | Ca <sup>++</sup> , mmol/L     | Preferred   | Yes   | 0.2-5  |
|  | Hct, %                        | Preferred   | No  | 12-75  |
|  | K <sup>+</sup> , mmol/L       | Preferred   | Yes   | 0.5-15.0   |
|  | Na <sup>+</sup> , mmol/L      | Preferred   | Yes   | 100-200  |
|  | pH                            | Required  | 6.500-8.000   | 6.500-8.000  |
|  | PCO <sub>2</sub> , mm Hg      | Required  | 5-250   | 10-150   |
|  | PO <sub>2</sub> , mm Hg       | Required  | 0-800   | 10-700   |
|  | Metabolites                   | Optional  | Not specified   | Not specified  |
|  | Others                        |   | Cl <sup>-</sup> , glucose, lactate  | Cl <sup>-</sup> , glucose  |
| - DERIVED  | a/A                           | Preferred   | Yes   | Yes  |
|  | A-aDO <sub>2</sub>            | Preferred   | Yes   | Yes  |
|  | BE                            | Preferred   | Yes   | Yes  |
|  | BE <sub>ecf</sub>             | Preferred   | No  | Yes  |
|  | Hb                            | Preferred   | No  | No: Yes  |
|  | HCO <sub>3</sub> <sup>-</sup> | Preferred   | Yes   | Yes  |
|  | ctO <sub>2</sub>              | Preferred   | Yes   | No: Yes  |
|  | SB                            | Preferred   | No  | No   |
|  | SO <sub>2</sub>               | Preferred   | Yes   | Yes  |
|  | ctCO <sub>2</sub>             | Preferred   | Yes   | Yes  |
|  | Others                        |   | No  | a-v, a-v/a   |
| <b>SO<sub>2</sub> &amp; CTO<sub>2</sub> ON/OFF</b> |                               |   | Available w/upgrade   | No: Yes  |
| <b>SAMPLE VOLUME, µL</b>                           | Normal                        | Required  | 125   | 100-130  |
|  | Micro                         | Preferred   | 95  | 75   |
| <b>INTEGRAL MULTI-WAVELENGTH OXIMETER</b>          |                               | Optional  | Available w/upgrade   | No: Yes  |
| <b>VISIBLE SAMPLE CHAMBER</b>                      |                               |   | Yes   | No   |
| <b>ANALYSIS TIME, SEC</b>                          |                               |   | 100   | 60   |
| <b>ELECTRODE MAINTENANCE</b>                       |                               | Minimal   | None  | None   |
| <b>DISPLAY</b>                                     |                               |   | LCD   | Colour touchscreen   |
| <b>PRINTOUT</b>                                    |                               | Optional  | Roll printer, optional ticket or line printer   | Roll printer   |
| <b>CALIBRATION</b>                                 |                               | Automatic, preferred  | Fixed (30 min, 1-point; 2 hr, 2-point, automatic, programmable)   | Automatic  |
| <b>STANDBY MODE</b>                                |                               |   | Yes   | No   |
| <b>INTERFACE</b>                                   |                               | Required  | RS232 (3), 1 parallel, TCP/IP converter   | RS232, TCP-IP  |
| <b>DATA MANAGEMENT</b>                             |                               | Required  | 5,000 patient records, patient demographics, 12x150 QC storage, Levey-Jennings plots <sup>3</sup>   | 250 patients, 250 cal, 250 events, 250 QC  |
| <b>USER-ENTERED DATA</b>                           |                               | Required  | Patient temp, FIO <sub>2</sub> , tHb, oxygen flow, patient/operator ID, sample source, date/time  | Patient temp, FIO <sub>2</sub> , tHb, oxygen flow, patient/operator ID, sample source, date/time   |
| <b>BAR-CODE READER</b>                             |                               | Preferred   | Optional  | Optional   |
| <b>PASSWORD PROTECTION</b>                         |                               | See other Specs   | Yes   | Yes  |
| <b>POWER REQUIREMENTS, VAC, Hz</b>                 |                               |   | 100/120/220/240, 50/60  | 100/120/220/240, 50/60   |
| <b>POWER CONSUMPTION</b>                           |                               |   | 400 VA  | 150 VA   |
| <b>HxWxD, cm (in)</b>                              |                               |   | 50.8x55.9x48.3 (20x22x19)   | 21.5x15.5x16 (8.5x6.1x6.3)   |
| <b>WEIGHT, kg (lb)</b>                             |                               |   | 29.5 (65)   | 34 (75); 44 (97)   |
| <b>LIST PRICE</b>                                  |                               |   | \$40.000 (860), \$49.900 (865)  | \$38.000: \$44.000   |
| <b>WARRANTY</b>                                    |                               |   | 1 year  | 1 year   |
| <b>OTHER SPECIFICATIONS</b>                        |                               | May require gas tank; should provide unauthorized access lockout. | Interfaces with co-oximeter, co-oximeter supplied with Model 865; onboard reagent-level indication; onboard automatic cleaning cycle actual and estimated shunt; 500 operator passwords; optional bar-code reader, external data management system. Meets requirements of CSA and UL. | Multiuse cartridges technology with 6 types of cartridges (3 menus, 2 sizes.); interface with data management. Meets requirements of CSA and UL. |

# Healthcare Product Comparison System

|  |                               | DIAMETRICS MEDICAL   | I-STAT  | PHILIPS MEDICAL   |
|--|-------------------------------|--|---|---|
|  |                               | IRMA SL BLOOD ANALYSIS SYSTEM  | PORTABLE CLINICAL ANALYZER <sup>7</sup>   | BLOOD ANALYSIS PORTAL SYSTEM  |
| <b>WHERE MARKETED</b>                              |                               | Worldwide  | Worldwide   | Worldwide   |
| <b>FDA CLEARANCE</b>                               |                               | Yes  | Yes   | Yes   |
| <b>CE MARK (MDD)</b>                               |                               | Yes  | Yes   | Yes   |
| <b>TESTS AVAILABLE</b>                             |                               |  |   |   |
| - MEASURED (RANGE)                                 | BP, mm Hg                     | 350-900  | Not specified   | 350-900 <sup>14</sup>   |
|  | Ca <sup>++</sup> , mmol/L     | 0.20-5.00  | 0.25-2.5  | 0.20-5.00 <sup>14</sup>   |
|  | Hct, %                        | 10-80  | 10-75   | 10-80 <sup>14</sup>   |
|  | K <sup>+</sup> , mmol/L       | 1.0-20.0   | 2.0-9.0   | 1.0-20.0 <sup>14</sup>  |
|  | Na <sup>+</sup> , mmol/L      | 80-200   | 100-180   | 80-200 <sup>14</sup>  |
|  | pH                            | 6.0-8.0  | 6.5-8.0   | 6.0-8.0 <sup>14</sup>   |
|  | PCO <sub>2</sub> , mm Hg      | 4-200  | 5-130   | 4-200 <sup>14</sup>   |
|  | PO <sub>2</sub> , mm Hg       | 20-700   | 5-800   | 20-700 <sup>14</sup>  |
|  | Metabolites                   | Not specified  | Not specified   | Not specified   |
|  | Others                        | Glucose (20-500mg/dL), BUN (3-150 mg/dL), Cl <sup>-</sup> (30-150 mmol/L), urea (1.1-53.4mmol/L)   | BUN (3-140 mmol/L), Cl <sup>-</sup> (65-140 mmol/L), glucose (20-450 mmol/L)  | BUN (3-150 mg/dL), Cl <sup>-</sup> (3-150 mmol/L), urea (1.1-53.4mmol/L) <sup>14</sup>  |
| - DERIVED  | a/A                           | No   | No  | No  |
|  | A-aDO <sub>2</sub>            | No   | No  | No  |
|  | BE                            | ± 99.9 mmol/L  | Yes   | ± 99.9 mmol/L <sup>14</sup>   |
|  | BE <sub>ecf</sub>             | ± 99.9 mmol/L  | Yes   | ± 99.9 mmol/L <sup>14</sup>   |
|  | Hb                            | 3.4-27.2 g/dL <sup>4</sup>   | Yes   | 3.4-27.2 g/dL <sup>15</sup>   |
|  | HCO <sub>3</sub> <sup>-</sup> | 0-99.9 mol/L   | Yes   | 0-99.9 mmol/L <sup>14</sup>   |
|  | ctO <sub>2</sub>              | No   | No  | No  |
|  | SB                            | No   | No  | No  |
|  | SO <sub>2</sub>               | 0-100%   | Yes   | 0-100% <sup>14</sup>  |
|  | ctCO <sub>2</sub>             | 0-99.9 mmol/L  | Yes   | 0-99.9 mmol/L <sup>14</sup>   |
|  | Others                        | No   | AG  | No  |
| <b>SO<sub>2</sub> &amp; CTO<sub>2</sub> ON/OFF</b> |                               | Yes  | No  | Yes   |
| <b>SAMPLE VOLUME, µL</b>                           | Normal                        | 200  | 65-85 (depends on cartridge type)   | 200   |
|  | Micro                         | 125  | NA  | 125   |
| <b>INTEGRAL MULTI-WAVELENGTH OXIMETER</b>          |                               | No   | No  | No  |
| <b>VISIBLE SAMPLE CHAMBER</b>                      |                               | Yes  | No  | Yes   |
| <b>ANALYSIS TIME, SEC</b>                          |                               | <90  | 120   | <90   |
| <b>ELECTRODE MAINTENANCE</b>                       |                               | NA (disposable)  | None  | NA (disposable)   |
| <b>DISPLAY</b>                                     |                               | LCD touchscreen  | LCD   | VGA   |
| <b>PRINTOUT</b>                                    |                               | Built-in roll printer  | Optional roll printer   | Thermal printer in monitor printer module   |
| <b>CALIBRATION</b>                                 |                               | Automatic before each test   | Self-calibrating cartridges (1-point)   | Automatic before each test  |
| <b>STANDBY MODE</b>                                |                               | NA   | Yes   | NA  |
| <b>INTERFACE</b>                                   |                               | RS232 modem  | To LIS/HIS  | RS232   |
| <b>DATA MANAGEMENT</b>                             |                               | IDMS, comprehensive data and POCT program management capabilities  | Stores 50 patient tests   | IDMS 3 optional <sup>16</sup>   |
| <b>USER-ENTERED DATA</b>                           |                               | User and patient ID, patient temp, QC lot numbers, QC ranges, Hb, sample type, sample site <sup>5</sup>  | Patient temp and ID, FiO <sub>2</sub> , sample type, operator ID, 3 user-defined fields   | User and patient ID, patient temp, sample type, entry with each test or same as last test   |
| <b>BAR-CODE READER</b>                             |                               | Yes  | No  | Yes   |
| <b>PASSWORD PROTECTION</b>                         |                               | Yes  | No  | No  |
| <b>POWER REQUIREMENTS, VAC, Hz</b>                 |                               | 100/240, 50/60 (charger, AC adapter) <sup>6</sup>  | 9 V lithium batteries (2)   | 100/120/220/240, 50/60  |
| <b>POWER CONSUMPTION</b>                           |                               | 1.2 VA   | None  | 9 W   |
| <b>HxWxD, cm (in)</b>                              |                               | 29.2x24.1x12.7 (11.5x9.5x5)  | 21x6.4x4.8 (8.3x2.5x1.9)  | 7.6x9.8x2.3 (3x3.9x0.9)   |
| <b>WEIGHT, kg (lb)</b>                             |                               | 2.4 (5.3)  | 0.53 (1.2)  | 0.6 (1.4)   |
| <b>LIST PRICE</b>                                  |                               | \$8.900  | \$5.000   | \$5.040   |
| <b>WARRANTY</b>                                    |                               | 1 year   | 1 year  | 1 year  |
| <b>OTHER SPECIFICATIONS</b>                        |                               | Interactive touchscreen; complete QC menu with internal EQC, QC lockout, user ID lockout, highly configurable settings, room-temperature cartridge storage; calibration before sample introduction; battery or AC-power; very low maintenance; portable to bedside. Meets requirement of CSA Class 2, EMC, ISO 9001 and UL544. | Handheld POC analyzer; disposable cartridges contain sensors, heating elements and buffered calibrants; no maintenance or gas tank required; used cartridge seals in waste. | Integrated with physiologic parameters in patient monitor; trended results in monitor; automatic patient-temp integration; flexible bedside mounting; interactive touchscreen; user-specified limits. |



| RADIOMETER  | RADIOMETER  | ROCHE DIAGNOSTICS   | ROCHE DIAGNOSTICS  | ROCHE DIAGNOSTICS   |
|---|---|---|--|---|
| ABL77 SERIES  | ABL700 SERIES   | COMPACT 3 <sup>7</sup>  | OMNI S3 <sup>7</sup>   | OMNI C <sup>7</sup>   |
| Worldwide   | Worldwide   | Worldwide, not USA  | Worldwide  | Worldwide   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| 0-800   | 450-800   | 300-800   | 300-800  | 300-800   |
| 0.20-5.00   | 0.20-10.0   | No  | No   | 0.1-6.0   |
| 10-80   | Derived   | No  | No   | 10-80   |
| 1.00-10.0   | 0.5-25.0  | No  | No   | 0.2-20  |
| 80-200  | 7-350   | No  | No   | 20-250  |
| 6.80-7.80   | 6.3-8.0   | 6.000-8.000   | 6.0-8.0  | 6.0-8.0   |
| 0-120   | 5-250   | 4-200   | 4-200  | 4-200   |
| 0-600   | 0-800   | 0-740   | 0-800  | 0-800   |
| Not specified   | Not specified   | Not specified   | Not specified  | Not specified   |
| Cl <sup>-</sup> (60-200 mmol/L)   | Cl <sup>-</sup> (7-350.0 mmol/L), glucose (0-60.0 mmol/L); see further in footnote <sup>17</sup>  | None  | ctHb (3-24 g/dL); O <sub>2</sub> Hb, HHb, COHb, MetHb, SulfHb (all 0-100%)   | Cl <sup>-</sup> (20-250 mmol/L), tHb (5-25 g/dL), SO <sub>2</sub> (60-100%)   |
| Yes   | Yes   | No  | Yes  | Yes   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Measured  | No  | Yes  | No  |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Yes   | No  | Yes  | Yes   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Ca <sup>++</sup> (7.40), ctO <sub>2</sub> , pH(T), PCO <sub>2</sub> (T), PO <sub>2</sub> (T)  | Up to 45, including AG, P50, Fshunt, Qx   | BB, cH+, pH(T), PCO <sub>2</sub> (T), PO <sub>2</sub> (T)   | pH(T), pHst (T), cH+, cH(T), FO <sub>2</sub> Hb <sup>21</sup>  | pH(T), nCa <sup>++</sup> , OSM, 35 calculated/derived values  |
| Yes   | Yes   | No  | Yes  | Yes   |
| ~70   | 195/95 syringe/capillary full panel   | 55  | 80   | 60  |
| No  | 35 <sup>18</sup>  | 25 (step mode)  | 40 blood gas/pH only   | NA  |
| No  | Yes   | No  | Yes  | No  |
| Yes   | Yes   | Yes   | Yes  | No  |
| <70   | 60-80   | 20  | 55   | 45  |
| None  | Prefilled membrane cartridges   | Zero-maintenance, optional premembraned electrode housing replacement   | Zero-maintenance electrodes and reference system   | Zero-maintenance electrodes and reference system  |
| TFT VGA colour touchscreen  | 10.4" TFT VGA colour touchscreen  | LCD   | 10" active colour touchscreen  | 5.7" flat colour touchscreen  |
| Thermal printer   | Thermal printer   | Thermal printer, optional ticket printer  | Roll printer, optional ticket or line printer  | Thermal printer with optional cutter  |
| Automatic, programmable 2-point   | Automatic, programmable 1- and 2-point  | Automatic, programmable 1- and 2-point  | Automatic, programmable 1- and 2-point   | Automatic, programmable 1- and 2-point  |
| No  | Yes   | Yes   | Yes  | Yes   |
| RS232, RJ45 Ethernet, 2-way   | Hardware, RS232, Ethernet port, software, 2-way ASTM, HL7, user-customized  | RS232 (3)   | RS232 (4); 1 parallel external keyboard, bar-code scanner  | RS232   |
| 500 patient results, 500 calibration results, 500 QC, 150 user IDs, floppy drive  | Defaults to 2,000 patient results, 1,500 QC, 3,000 system messages, 1,000 calibration results   | Onboard QC, stores last 3 patient results, error logbook  | Onboard data manager stores >50,000 patient results, 1-year QC, calibration and maintenance logs   | 10,000 patient records, 1-year QC/maintenance logs, 6 months calibration logs   |
| Patient ID, operator ID, draw site, accession number, time, type, temp, GIU correction, FiO <sub>2</sub>  | Patient temp, ID, height, weight, sex, age, name; tech ID; dept; sample type; FiO <sub>2</sub> ; sampling time <sup>19</sup>  | Patient temp, FiO <sub>2</sub> , RQ, Hb (adult or fetal), P50, tHb  | Patient name, ID, sex, DOB, physician, blood type, Allen test, puncture site, sample source <sup>22</sup>  | Patient ID, date, time, 65 patient and sample input fields  |
| Yes   | Yes   | Yes   | Yes  | Yes   |
| Yes   | Yes   | Yes   | 4-level security   | Yes   |
| 100-240, 50/60  | 100-240, 50/60  | 100-240, 50/60  | 100-240, 50/60   | 100-240, 50/60  |
| Not specified   | 250 VA  | 65 VA, max 110  | 160 VA   | 110 VA  |
| 33x20x23 (13x7.9x9.1)   | 40x70x55 (15.7x27.6x21.7)   | 34x34x31.5 (13.4x13.4x12.4)   | 60x53x47 (23.6x20.9x18.5)  | 45.7x35.6x41 (18x14x16.1)   |
| 7.2 (16)  | 26-30 (57.3-66.1)   | 13 (28.7)   | 40 (88)  | 23 (50.7)   |
| Not specified   | Not specified   | \$16,995  | \$39,900   | \$18,000  |
| 1 year  | 1 year  | 1 year  | 1 year   | 1 year  |
| Portable; customizable configuration and test panels; QC and user lockouts; floppy drive; LIS/HIS interface; bar-code reader; disposable multitest sensor cassette and calibration pack. EMC emission and immunity. Meets requirements of TUV and UL. | Onboard automatic QC module; onboard gas bottles; onboard acid-base chart; disposable waste system; configurable from 3 to 17 parameters; help function with videos; LIS/HIS interface; remote control via RADIANCE from PC; EMC emission and immunity; whole blood Tbil. Meets requirements of CSA and UL. | User interface; diagnostic program; power-failure protection; interface for co-oximeter/AVL electrolyte analyzer/ticket printer/computer/bar-code scanner/service modem; password protection; standard or SI units. Meets requirements of CE and CSA. | Keyboard; random-access test selectivity; onboard help functions; sealed waste container; no gases needed; upgradable to add electrolyte or metabolite module; optional remote diagnostics via modem; optional AutoQC unit for automatic QC measurement and evaluation with auto parameter un-/lock features. Meets requirements of CSA and OVE. | Automatic sample aspiration; clot and air detection; QC and user lockout; OMNLink remote control; optional auto QC module with 120 ampules. |

# Needs of the families of dying patients

Professor Wilmer and his colleagues report a study showing that honesty, assurance that patients are not suffering and liberal visiting hours are the most important needs of relatives of patients who are dying in intensive care.

## Introduction

Caring for families is an integral part of intensive care medicine. In previous studies we assessed the degree of anxiety and the needs of relatives of patients hospitalised in the Intensive Care Unit (ICU) (Bijttebier et al. 2001; Delva et al. 2002). These and other studies showed that the state of anxiety of relatives of patients hospitalised in ICU is extraordinarily high, mainly because most perceive admission to ICU as a very frightening and stressful event (Azoulay et al. 2001; Lee & Lau 2003; Leske 1986; Molter 1979; Ward 2001; Zazpe et al. 1997). These studies also revealed that relatives experienced recognisable and specific needs. The most important needs were for information, assurance and proximity. Identifying these specific needs led to a new integrative approach within our team of caregivers emphasizing improvement and more skilful communication with relatives.

In our Medical Intensive Care Unit (MICU), the annual mortality rate is approximately 25%. In more than 98% of cases the death of the patient is predictable, and in almost all cases the death of the patient is preceded by extensive communication with the relatives. We felt that the needs of relatives in these very specific, critical, end-of-life care situations deserved further investigation. We therefore assessed the needs of patients' relatives, after they had been told that their loved one was going to die. Additionally we studied characteristics of the relatives and patients, which may influence the needs of the relatives.

## Methods

This study was completed between May 2002 and April 2003 in the MICU of the University Hospital Gasthuisberg, at the Catholic University of Leuven. The MICU is one of several intensive care units in our 1700-bed hospital. The unit has 17 beds and admits approximately 650 patients per year.

Once relatives had been informed by the treating physician that the situation had become untenable and that the patient was going to die, they were contacted by the social worker or head nurse of the MICU and informed about the purpose of the study. Inclusion criteria for the study were that relatives 1) had been informed of the imminent death of the patient, 2) were older than 18 years, 3) could read and write in Dutch, and 4) gave informed consent. If eligible, the needs of the relatives were assessed

with the Critical Care Family Needs Inventory (CCFNI), a self-reporting questionnaire with 45 items, scoring on a 4-point Likert scale ("not important" to "very important") (Bijttebier et al. 2000; Molter 1979). The questionnaire assessed 5 categories of information: needs for information, comfort, support, assurance, and accessibility/proximity to patients. Additionally, relatives were asked questions on their possible needs (n=14) and on social and demographic characteristics. The data were analysed statistically using averages, correlation coefficients (CC) and variance analysis.

## Results

### Characteristics of patients and their relatives

Data were collected prospectively from 101 relatives of 45 patients (average = 2.2 contacts per patient). The mean age of the patients was 65.5 yrs (20 women), and the mean age of the relatives was 49 yrs (range 20-77, 40 women). The highest qualifications attained were high school diplomas for 73% of the respondents and university degrees for 27%. This was the first admission to an ICU for 18 of the 45 patients and for 4 patients it was the first admission to a hospital. All patients died within 1 to 360 hours (average 30 hours) following the first contact between the social worker or head nurse and the relative.

### Relatives' needs

The individual items (from the original 45) with the ten highest and the ten lowest scores are summarized in table 1. Scores for the five categories focused in the CCFNI were derived from the item scores in each category. The need for information scored highest (3.68), followed by assurance (3.33), proximity (3.16), and support (2.71). The need for comfort scored lowest (2.54).

### Influence of socio-demographic variables of relatives or patients on relatives' needs

Need for information or for proximity: Need for information or proximity was independent of variables such as age of the patient, age or gender of the relative, or the number of the patient's previous ICU admissions. Need for assurance: older relatives needed more assurance about the comfort of the dying patient than younger relatives (CC 0.22, p=0.03). Need for support: the relatives of younger dying patients needed support more than those of older patients (CC=-0.21, p=0.04). Need for comfort: relatives of patients who had been



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admitted to ICU repeatedly needed comfort more than those of patients who had been admitted to ICU for the first time (t-test,  $p=0.02$ ). Similarly, women relatives needed comfort more than men (t-test,  $p=0.04$ ).

### Summary

This study explores the needs of relatives of patients who are hospitalised in intensive care after being told that their loved one is going to die. The data show that the most important needs are honest and understandable information about the patient and his or her prognosis, assurance that the patient does not suffer

and is being given the best medical care, to be able to communicate with caregivers about death itself, and to see their loved one frequently. These needs are comparable to the needs of relatives of patients who are hospitalised in the ICU, but not necessarily predicted to die (Delva et al. 2002). The only need which scores as more important in this study is the need for proximity, that is, for the relative to be able to see the patient more frequently.

Not unexpectedly, relatives of younger dying patients needed support more than relatives of older dying patients. On the other hand, older relatives needed assurance about the comfort of their dying relative more than younger relatives. Similarly, women experienced the need for comfort more than men. These observations can be used to differentiate the care for specific groups of relatives, focussing on their specific needs.

The need for family conferences as a focus to improve communication about end-of-life care in ICU has been emphasized earlier (Curtis et al. 2001). Previous research has also shown that adequate communication, good decision making, respect and compassion are key determinants to family satisfaction with critical care patients (Clarke et al. 2003; Heyland et al. 2003;

Kirchhoff et al. 2004). Based on the present data, we propose the following guidelines for good clinical practice to care for relatives in end-of-life situations:

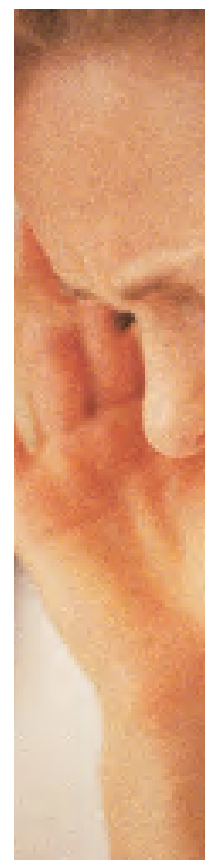
1. The treating physician should communicate clearly, honestly and with empathy about the impending death of the patient.
2. The nurse should participate actively in the process of communication, evaluate the quality of the communicative process and respond to ongoing needs of the families.
3. Visiting hours should be liberal in end-of-life situations.
4. There should be daily contact between the relatives, social worker, nurse and physician. The team of caregivers should coordinate information delivery on the status of the patient, in advance.
5. Continuous attention should be paid to how individual relatives cope and apparent needs should be addressed and attended to wherever possible.

We believe that this approach will not only alleviate relatives' acute anxieties and needs, but may also foster the healing process at the close of life. Good ICU management includes good protocols for caring for patients' relatives. Regular training within the team to improve and harmonise communication skills should be part of the routine organisational program.

**Table 1: 10 highest and 10 lowest item scores from the Critical Care Family Needs Inventory collected from 101 relatives of 45 patients**

| TOP 10 SCORES OF THE QUESTIONNAIRE    |   |      |
|---------------------------------------|---|------|
| 1                                     | To get an honest answer to one's questions  | 3.99 |
| 2                                     | To be assured that the patient does not suffer                                      | 3.97 |
| 3                                     | To be assured that the best possible care is being given                            | 3.93 |
| 4                                     | To know the prognosis   | 3.90 |
| 5                                     | To be called at home with information about changes in the condition of the patient | 3.85 |
| 6                                     | To be given understandable explanations   | 3.84 |
| 7                                     | To know specific facts concerning the patient's evolution                           | 3.84 |
| 8                                     | To feel that hospital personnel care about the patient                              | 3.82 |
| 9                                     | To talk about the possibility of the patient's death                                | 3.80 |
| 10                                    | To see the patient frequently   | 3.73 |
| LOWEST 10 SCORES OF THE QUESTIONNAIRE |   |      |
| 50                                    | To have friends nearby for support  | 2.54 |
| 51                                    | To have someone to help with financial problems                                     | 2.46 |
| 52                                    | To have the waiting room near the patient   | 2.43 |
| 53                                    | To have another person with you when visiting ICU                                   | 2.35 |
| 54                                    | To be told about chaplain services  | 2.32 |
| 55                                    | To be offered coffee near the patient's bed   | 2.29 |
| 56                                    | To help with the patient's physical care  | 2.16 |
| 57                                    | The possibility to have decent meals in the hospital                                | 2.10 |
| 58                                    | To have comfortable furniture in the waiting room                                   | 2.05 |
| 59                                    | Being encouraged to cry   | 1.63 |

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)



# Open Visiting Hours in the Adult ICU

Open visiting hours are part of a global policy to help families cope with the stress and difficulties of having a relative hospitalized in an ICU, especially during the patient's end-of life.

## Introduction

The usual consequences for the family of hospitalization of a relative in an ICU include stress, anxiety, loss of communication, and disorganization of family life. The family needs to adapt to a hostile and unknown environment, which is highly technical and has strict organizational rules. The great majority of ICUs have restricted visiting policies, specifying hours and number of people (Quinio et al. 2002). These rules contribute to a feeling of exclusion in families, for which reason we advocate open visiting hours.

## Visiting hours and meeting the needs of families

Several studies have shown the advantages for families and patients of allowing visiting at any time. Such a policy reduces stress and anxiety, encourages better communication, allows families to become more involved in the patient's care and enables them to organize visits alongside their usual commitments (Ramsey et al. 1999; Roland et al. 2001; Simon et al. 1997). Open visiting hours does not create organizational problems if the care constraints of an ICU are fully explained to families. Drawing up a 'contract' with families about visiting hours has been suggested (Moseley and Jones 1991; Simon et al. 1997).

When a patient reaches the end-of-life stage, it is most important to enable families to be present during the last days. All families should systematically be offered the possibility to stay continuously with or near their relative, if they so wish, in order to say goodbye (Carlson et al. 1998; Younger et al. 1984). Though changing visiting hours is stressful for the nursing staff (Roland et al. 2001), the worry about families being continuously present can be reduced if the decision is made and supported by everyone (Mosenthal et al. 2002; Simpson et al. 1996).

Equally important to allowing more people to visit (relations, friends) without restrictions, staff should also remain vigilant to prevent any possible family feuds. It should be remembered that not all families may wish to remain with their relative until the end, but all need to know that they will be informed whenever the patient's health deteriorates and/or death becomes imminent.

Open visiting hours need to be accompanied with additional measures:

- Encouraging family members to communicate with their loved one: families often express their sadness and

regret at not being able to verbally communicate with the patient and feel deprived of the opportunity to say their last goodbyes. The family must be encouraged to speak to and touch their loved one, say goodbye and perform any rituals desired (Mosenthal et al. 2002);

- Preserving privacy: the family needs to be alone with the patient to talk and to share memories. It is important to leave people time on their own, if they wish.

## Personal experience and evaluation of this type of support for families

Similar to most adult ICUs, visiting hours in our tertiary care hospital 12-bed medical ICU were restricted to two hours per day until 2000. There was not much flexibility, even when a patient was at an end-of-life stage, and nearly all patients died without their relatives close to them. The medical and nursing team felt that this was not meeting the families' needs during this painful period.

To respond to what we felt was a shared expectation, we introduced several measures, starting in January 2001, which are systematically offered to families of end-of-life patients:

- 24-hour open visiting policy;
- Number of people in the patient's room extended to four;
- Possibility for a member of the family to sleep in a "family room," which was created for the purpose, with drinks and biscuits available;
- Flexible nursing organization to encourage privacy without compromising quality of care;
- Allowing families to reduce the lighting, play music softly, and practice religious rituals, if they wish.

We evaluated family satisfaction of both visiting policies in 2002 (Boles et al. 2004). The closest relatives of the 196 patients who died in our ICU between January 1999 and December 2001 were sent a questionnaire. We received 70 answers (35.7%).

Twenty-nine answers (42%) concerned patients who had died in 1999 and 2000, before the opening of visiting hours: 87.5% of family members felt great pain at not being present with their loved one at the moment of death. This suffering was often expressed in aggressive wording. Up to three years later, some people felt "lost" and unable to progress through the bereavement process. Satisfaction with the team at the moment of death was low 37.5%.

Thirty five answers (50%) concerned patients who had died in 2001, for whom families had been able to stay



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Families need a warm human relationship  
with respect for their own wishes  
and those of their loved one ...



with their relative during the last moments of the patient's life. Improved communication with staff was reported by 76.5% of family members, linked with an increased availability of staff (67.7%). Seventy percent of family members felt that they had been prepared for the death of their loved one and expressed their feelings using words such as "calm" and "compassion".

Families did not want more friends and family members to be present at the same time in the patient's room (60.2%), didn't mind wearing a white blouse (72%) and did not wish the number of times members of staff entered the room to be reduced (59%).

All staff favoured the open visiting hours for families of terminally ill patients. Reasons given were the impression of improved communication and warmer relationships with families and more time to support families without jeopardising quality of care. Without being

asked, staff members were able to change treatment routines to meet the families' needs.

### Conclusion

Families need a technically competent medical team, comprising members who can also build a warm human relationship and who will respect both their wishes and those of their loved one, when he or she is in an end-of-life stage.

Opening visiting hours and developing flexibility in nursing organization, as well as listening, supporting and providing respect are complementary, to help families to remain present to the end and to cope with the death of a relative in the ICU. Let us not forget that "families are not just visitors to intensive care" (Molter 1994).

**"families are not just visitors to intensive care"**



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**First  
announcement**

# Managing staff levels: a prerequisite to control rate and appropriateness of ICU resource use

Professor Iapichino and his colleagues have designed a tool to measure the rate and appropriateness of nursing coverage in intensive care units (ICU), as a proxy for total use of resources. This fast and simple method for use within the ICU computes the optimal use of resources, based on fixed human resources or a fixed number of beds.

## Introduction

Intensive Care Units (ICUs) are not all equivalent. One important difference between them concerns the severity of illness of patients and consequently the complexity of treatments and use of resources. As the provision of intensive care depends mainly on the availability of nurses, figures for this resource serve as a proxy for overall resource consumption.

Historically, the nursing workload at patient level has been measured based on level of clinical assistance (TISS, TISS 28, NEMS) (Cullen et al. 1974; Miranda et al. 1996; Miranda et al. 1997) resulting in cumulative points, such as 40-50 points representing 24 h of nursing workload (Cullen et al. 1974; Iapichino 1991; Miranda et al. 1996; Miranda et al. 1997) or in minutes of workload (TOSS, NAS) (Iapichino 1991; Miranda et al. 2003). Quantifying nursing workload and defining the average number of patients that a nurse can manage defines the average complexity of care required by patients under treatment. Four levels of care were first defined by the Bethesda Consensus Conference in 1981 (Consensus Conference: Critical Care Medicine 1983). Miranda and Langrehr revised these to define three levels of intensive care (1990), and these levels were later endorsed by a task force of the European Society of Intensive Care Medicine (Ferdinande 1997).

Recent studies have shown that use of resources in European ICUs is often inefficient. A major reason is the “waste” of nursing manpower (Iapichino et al. 2000; Moreno & Miranda 1998), which constitutes the largest part of resources allocated to the ICU. “Waste” is measured by comparing the capacity for delivering nursing work with work actually delivered (Moreno and Miranda 1998). “Annual delivery” is calculated based on a therapeutic index (Miranda et al. 1997) summing the scores obtained daily at patient level; “annual capacity” is derived from the total number of nurses in the ICU, taking into account the amount of work (total index score) possible in a year by one full-time nurse (Miranda and Langrehr 1990). Originally designed for research purposes, this method is time-consuming and laborious, and therefore demands more than the normal efforts expected for

management purposes in ICUs. However, assuming that such studies might enable ICU managers to monitor practice patterns and determine the rate and appropriateness of human and fixed resource use, we have designed a new approach to quantify the provision of and demand for nursing manpower on a daily basis (Iapichino et al. 2004).

## Description of the tool

The approach quantifies the mean “actual nurse assistance” devoted to the patients over a defined period of time. Recording the number of occupied beds and classifying the use of nurses at patient level (provided level of care) is mandatory for each day of the test period. To offer a real-time and friendly-to-use instrument for the frequent appraisal and guidance of resource allocation in the unit, we propose only two levels of care.

We used six out of nine NEMS items (Miranda et al. 1997) to define two grades of intensity/complexity of care at patient level (Iapichino et al. 2001). The level is defined as highly-intensive/complex (HLC) if monitoring is coupled with active respiratory support, and/or multiple vasoactive drugs, or less active support of at least two organs (e.g. supplementary ventilatory care, single vasoactive drug, dialysis). All other combinations are classified as low-level care (LLC). LLC corresponds to level of care I and HLC includes levels II and III from the classification of ICUs (Miranda and Langrehr 1990; Ferdinande 1997).

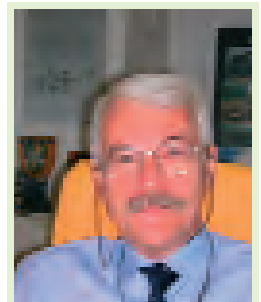
## Method

a) The instrument is devoted to medium-high level ICUs, with HLC beds sometimes used for LLC, even if only before patients are discharged from ICU (Iapichino et al. 2002). It might also be used to evaluate a single organisation/performance or for benchmarking to audit several ICUs (Iapichino et al. 2004).

b) Data can be cross-sectionally collected on certain days in the week (e.g. Monday, Tuesday, Thursday and Saturday) to sample the weekly patterns of the case mix during a 2-3 month period or year to capture seasonal variations.

c) The application of the tool requires some basic assumptions which need to be defined at ICU level:

- the list of the equipment necessary to provide active



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**Table 1. Use of the Instrument in three different ICU scenarios**

|   | ICU A                 | ICU B                | ICU C                 |
|---|-----------------------|----------------------|-----------------------|
| Nurse shifts in 24h   | 5                     | 3                    | 3                     |
| Study period: days  | 30                    | 30                   | 30                    |
| Available nursing days  | 150                   | 90                   | 90                    |
| Delivered patient treatment days  | 175                   | 136                  | 187                   |
| Actual nurse assistance   | 175/150=1.167         | 136/90=1.51          | 187/90= 2.08          |
| Delivered HLC/LLC treatment days  | 95/80                 | 80/56                | 152/35                |
| Theoretical appropriate patient/nurse ratios: HLC; LLC                            | 1:1; 3:1              | 1:1; 3:1             | 2:1; 3:1              |
| Theoretical appropriate number of nurses for HLC+LLC - provided treatments        | 95+80/3               | 80+56/3              | 152/2+35/3            |
| Theoretical nurse assistance  | 95+26.6= 121.7        | 80+18.7= 98.7        | 76+12= 88             |
| Nursing resource use  | 175/121.7= 1.44       | 136/98.7=1.378       | 187/88= 2.135         |
| Rate of utilization (%)*  | 1.167-1.44= -0.273    | 1.51-1.378= +0.133   | 2.08-2.13= -0.05      |
| <b>Theoretical maximum number of HLC patient-days (all nurses devoted to HLC)</b> | <b>5x30x1= 150</b>    | <b>3x30x1= 90</b>    | <b>3x30x2= 180</b>    |
| <b>HLC utilization rate (%)</b>   | <b>95/150 = 63.3%</b> | <b>80/90= 88.9%</b>  | <b>152/180= 84.4%</b> |
| <b>Patient treatment days without HLC provided</b>                                | <b>150-95 = 55</b>    | <b>90-80= 10</b>     | <b>180-152= 28</b>    |
| <b>Theoretical maximum number of possible LLC patient-days</b>                    | <b>55/1x3= 165</b>    | <b>10/1x3= 30</b>    | <b>28/2x3= 42</b>     |
| <b>LLC utilization rate (%)</b>   | <b>80/165= 49.0%</b>  | <b>56/30= 186.6%</b> | <b>35/42= 83.3%</b>   |

\* Actual/Theoretical nurse assistance x 100

life-support (monitoring, ventilation, titrated infusion capacity); the theoretical “appropriate patient to nurse ratio” for HLC (e.g. 1, or 1.5 or 2), and for LLC (e.g. 3). This can be defined at the unit level according to case mix, therapeutic strategies and nursing workload.

- the need for care is constant around the clock. This assumption limits the nurse to patient ratio used to that of the lower staffed shift (usually the night shift) to provide a constant value for the whole day. This number multiplied by the number of days during the test-period provides the “available nursing-days” during the test period: available nursing days = night-nurse to patient ratio x days in test period.
- per day each bed can only serve one patient with only one level of care. If a bed is used within the same day by more than one patient with different levels of care, or by a single patient with modification of the level of care, the highest level is selected. This provides the number of patients treated each day or “delivered treatment days” during the test period. Delivered patient treatment days are recorded separately as HLC or LLC.

**Calculating rate of resource use at ICU level**

- The “actual nurse assistance” is computed by dividing the total number of delivered patient treatment days by the total number of available nursing days in the period: actual nurse assistance = delivered patient treatment days/ available nursing days.
- The “theoretical number of nurses” required to manage the treatment days delivered incorporates the level of care for each patient treatment day (HLC and LLC

and attributes the appropriate assistance (number of nurses) as defined by the ICU staff, i.e. the “theoretical appropriate patient/nurse ratio”.

- The “theoretical nurse assistance” is computed by dividing the overall actual delivered patient treatment days by the theoretical number of nursing days needed to manage the actual HLC and LLC patient treatment days delivered during the test-period (see table 1).

d) The “nursing resource use” in the test period is calculated as the difference between the actual and theoretical nurse assistance (delivered patient treatment days/ nurse ratios). A positive difference indicates a higher number of patient treatment days delivered than appropriate for the nursing resources, i.e. over-utilization, and a negative difference indicates a lower number of patient treatment days than appropriate with the available nursing resources, i.e. under-utilization.

**Calculating appropriateness of resource use**

Records of the delivered patient treatment days as HLC or LLC allows a separate calculation of utilisation rate.

- The “theoretical maximum number of HLC patient treatment days” is computed as if all members of the nursing staff were devoted to HLC (see table 1).
- Knowing the total number of delivered HLC days and the theoretical maximum number of HLC days, the percentage of “resources used for HLC” can be calculated.
- For nursing days not used for HLC, due to empty beds or beds dedicated to LLC, it is possible to calculate from the remainder (i.e. the patient treatment days without HLC), the “theoretical maximum availability of LLC





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# Is rescheduling surgery a viable solution to triage?

Professor G. Van den Berghe, Dr J. Albers and Professor C.-F. Vahl present their opinions on whether rescheduling surgery is a viable solution to triage. Professor Jukka Takala's comment on these viewpoints follows, in which he explains the solutions practiced in his own ICU.

## Dr Albers and Professor Vahl Rescheduling planned surgical operations is not a viable solution to clinical triage

We first define the terms we use: "Rescheduling surgery" means the decision of the therapeutic team not to operate on a patient although a clear surgical indication exists. "Triage" in this context means the decision of the therapeutic team to discharge a patient from the ICU although no clear indication exists. The therapeutic team seems to be left alone within this bipolar arena. The above mentioned problem is one symptom of a medical environment characterized by restricted resources and a high number of emergency cases. In these circumstances the quality of team processes becomes increasingly important. In clinical reality however, separated fields of interest frequently exist between anaesthetists, intensivists, surgeons, and nurses. The subprocesses of care differ, and in extreme cases, are not linked in an optimal way.

The operation represents the centre of the surgical production line. Rescheduling cardiac surgery is equivalent to increasing the risk of a patient operated on at a later point in time. Achieving a fair balance between triage and rescheduling involves the whole team of the surgical production line. This includes surgeons performing less invasive procedures, anaesthetists using fast track anaesthesia wherever possible (Djaiani et al. 2001), ICU experts performing ICU triage, and trained outreach teams caring for ward patients.

The decision for discharge from the ICU with its consequences is highly dependent on who decides, and on the patient's status. When intensivists are involved in ICU discharge decision-making, the patient outcome is improved (Yoon et al. 2004). To evaluate outcome, the intensivist may rely on his/her own experience and on several sources of evidence. Pre-discharge organ dysfunction score is a predictor for in-hospital death after ICU discharge, as shown in a trial with nearly 3000 patients (Moreno et al. 2001). In a retrospective analysis of cardiac surgery patients readmitted to ICU, the factors non-elective surgery and higher required inspiratory oxygen upon discharge were the strongest predictors for readmission (Chung et al. 2002). In a large Canadian readmission study, cardiac surgery patients with preoperative renal failure or who required ventilation for more than 24 hours were at highest risk of ICU

readmission (Bardell et al. 2003). Taken together, unstable vital signs are the most often reported reasons for readmission (Rosenberg and Watts 2000). Readmission to the ICU is associated with higher mortality. Based on this evidence, qualified intensivists should (1) decide on discharge (2) rate the severity of illness (3) identify individual risk factors (4) provide information to the ward personnel, and (5) provide assistance. This latter represents the most important point. It includes personal involvement and teaching, for example by providing FCCS courses.

The ICU of the Department of Cardiothoracic and Vascular Surgery of the University of Mainz is a ten-bed closed unit, headed by a full-time intensivist with qualifications in intensive care medicine and cardiac surgery. The therapeutic team further comprises a second full-time intensivist, a junior assistant, highly trained nurses, and two physiotherapists. Our experience, education and training have led to our understanding that intensive care begins in the OR and continues even after discharge from ICU.

The interdisciplinary decision regarding rescheduling surgery versus patient triage remains a team challenge. In a well-trained therapeutic team, the decision will almost always be not to delay surgery.

## Professor Van den Berghe Rescheduling elective surgery can be limited by using appropriate management tools, but remains unavoidable facing a tight budget for intensive care and scarcity of ICU nurses

A surgical ICU (SICU) hosting patients from an active elective cardiac surgery program as well as emergency admissions for trauma, solid organ transplantation and life-threatening complications after all types of surgery, requires a triage system. Obviously patients with life-threatening disorders should receive immediate and optimal intensive care. To accommodate these needs, rescheduling elective (non-emergency) surgery patients presents a possible solution. Rescheduling elective surgery remains extremely unpleasant for the patient and his/her surgeon and also costly for the hospital. Although every attempt should be made to avoid rescheduling, it is not always realistically possible.

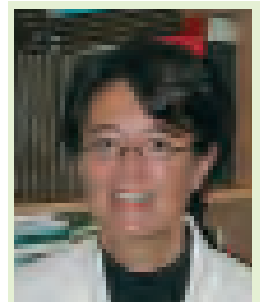
Our 56 bed, tertiary/quaternary referral SICU serving a large 1900 bed hospital functions within a system of

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multidisciplinary, combined elective/emergency admissions and works with a nurse to patient ratio of 1:2 and a virtual 100% occupancy. We adopted this approach due to the strength and high quality of multidisciplinary intensive care and in view of the scarcity of well-trained ICU nurses/physicians and the high staffing costs. Empty ICU beds reflect huge financial losses for the hospital. The 100% occupancy is only an option when a limited number of “buffer-beds”, equipped and staffed for mechanically ventilated patients, are available in the post-operative recovery room and the emergency department, for exceptional patient overflow.

Our ICU admits +/- 2200 ventilated patients per year, of which 60% are from the elective paediatric (complex congenital cardiomyopathies) and adult (combined valve/coronary procedures for patients with high euro-scores, corrections of congenital anomalies in adults and transplant procedures) cardiac surgery program. We have a 2.3% re-admission rate for emergencies due to complications after this, initially elective, phase. This group of patients occupies < 40% of the ICU beds because the risk of prolonged intensive care stay is much lower than for emergency admissions. In order to comply with the sometimes opposing goals of serving elective and emergency admissions, we designed a pragmatic management tool for optimal triage. Although not evidence-based, the instrument appears to optimise our cost-effective, high-quality service to critically ill patients. We set a certain number of ICU beds as a “virtual slot” for the cardiac surgery program and we evaluate the validity of this “slot” on a daily, weekly, monthly and yearly basis. This is necessary to quickly detect external factors forcing us to revise the size of the slot. Examples of such external factors are the evolution towards more non-invasive procedures performed by cardiologists and flow-through problems on the normal wards. Likewise, we critically evaluate the implications of setting this “slot” on the quality of care and flow-through of patients admitted for complications after other types of surgery. Detecting problems quickly allows these to be resolved before they generate substantial impact. We allow temporary over- and under-use of the elective “slot”, with a monitoring and correction system applicable to both parties’ planning. Hereby, an overall fixed number of beds for patients in the elective program can be guaranteed.

A key to success in this system is a relatively constant number of elective patients being presented from the inflow-side, per day and per week. Primarily, this implies a regular and even planning by surgeons and anaesthesiologists in the operating room (OR). Simultaneous

absence of all members of the surgical team for a scientific meeting, for example, inevitably evokes a temporarily reduced number of scheduled patients, which – in a 100% occupancy system – results in a progressive occupancy of the elective beds by other emergency admissions. As these patients require a longer ICU stay, it takes several weeks to “free” the “slot” again for the elective program. Another, less avoidable reason for reduced availability of beds for the elective cardiac surgery program is a sudden increase in the number of patients receiving solid organ transplantation, a program that does not tolerate organ refusal for ethical reasons.

A key to limit unnecessary waiting for a “go” for the OR staff and for patients on the wards, is to guarantee a stable minimum number of elective surgery admissions per day. Setting this number realistically requires a detailed analysis of the bed-occupancy of the ICU. With this number of guaranteed admissions, the morning shift in the OR can always start work without delay, which allows a cost-effective management of nursing time in the OR. During the course of the morning, the decision on the additional number of elective patients that can be admitted to the ICU that day is communicated to the OR staff.

This strategy, even within a virtually fixed slot, limits rescheduling of elective surgery to the minimum. Nevertheless, rescheduling remains the unavoidable price to pay for a 100% occupancy in ICU. In our system, on a yearly basis, the “virtual slot” is occupied exactly as planned. For more than 2/3 of the year, a full or more than full occupation of the elective surgery slot is achieved; in 108 days of 2004, the slot was not fully occupied. For 3 out of 4 of such occasions, this was due to an unexpected lower inflow from the elective cardiac surgery program. For only 1 out of 4 times, overcrowding of the ICU by other emergencies was the reason, which resulted in a global need for rescheduling less than 1 out of 10 patients planned for elective cardiac surgery. Of all the emergency admissions in 2004, 12% of the requests needed to be delayed due to lack of ICU bed availability. The latter problem was fully balanced against the number of patients who were ready for ICU discharge, but did not have a bed available on the regular ward.

We consider this an acceptable compromise for a high quality, cost-effective and ethical ICU management, although optimisation of outflow to regular wards has potential for further improvement. Any system that does not allow rescheduling of elective surgery will either require an excess of ICU beds and nursing staff and therefore be less cost-effective, or will compromise the quality of patient care.

We set a certain number of ICU beds as a “virtual slot” for the cardiac surgery program and we evaluate the validity of this “slot” on a daily, weekly, monthly and yearly basis.

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)

# Allocation of ICU resources: first come first serve vs. service when needed

In response to the preceding comments by Professor Van den Berghe, Dr Albers and Professor Vahl, Professor Takala discusses their viewpoints and explains the solutions practiced in his own ICU.

Intensive care services within a general hospital system serving a population base must fulfil dual needs: those for emergency admissions from the referral population and the hospital itself, and those needed for planned (elective) surgical and other interventions. The actual organisation of intensive care services for the population in question should be taken into consideration, when allocation of resources is discussed: who are the service providers for intensive care – one vs several hospitals, ICUs within the hospitals, specialties providing ICU services, and the collaboration between the service providers. The number of elective ICU admissions and the necessary resources can be planned, and should be clearly linked to the strategy of the hospital system: if the number of elective operations done is consistent with the strategy of the hospital, then the corresponding amount of resources for postoperative intensive care should be available for these operations. This, as self-evident as it may sound, would logically have the consequence that rescheduling elective surgery due to lack of ICU-resources should never happen. This idealistic-sounding concept is complicated in reality by several factors.

First, in contrast to elective admissions with relatively predictable lengths of stay, the need for emergency admissions has a relatively large day-to-day variability and highly variable length of ICU stay.

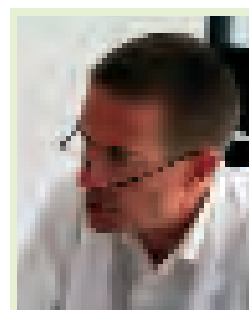
Second, financial and personnel availability constraints make it unreasonable to always have resources available for the maximum demand. Therefore, a strategy for responding to the inevitable fluctuation in the need for ICU services, largely caused by emergencies, must be available. In this issue of ICU Management two different views are presented on using the rescheduling of elective surgery as a triage tool for intensive care services availability. These views clearly demonstrate some of the key issues in resource allocation, while the consequences of both strategies for the whole patient care process and resource allocation within the hospital or hospital system receives only limited consideration.

A carefully planned elective surgical production line produces a foreseeable demand for intensive care resources. Also with this scenario, inevitable fluctuation in length of stays will cause day-to-day and week-to-week variation in the demand. Either the ICU must have

sufficient capacity to meet the peak demand, or there must be flexibility in the production line to shift the available production resources to surgery not requiring intensive care during times when the ICU capacity is exhausted. Prof. Van den Berghe considers such high ICU capacity as too expensive for the hospital and recommends rescheduling of elective surgery as the optional tool for resource management. Dr. Albers and Prof. Vahl argue that rescheduling increases the risk for the patient and that optimizing patient management and discharge decisions including extending care support to wards, helps to avoid rescheduling. Although not explicitly expressed, I assume that Dr. Albers and Prof. Vahl have adjusted their ICU-capacity to meet, at least in part, the “average” extra needs due to fluctuation in both the elective and emergency intensive care. Prof. Van den Berghe, on the other hand, argues that the ICU capacity must be occupied up to 100 %, and buffer zones created elsewhere in the hospital, providing mechanical ventilation in the recovery room and emergency care area, and that additionally, elective surgery is cancelled. In her hospital this results in less than 10 % of elective cardiac surgery being rescheduled, and 12 % of emergency admissions being delayed due to ICU bed shortage.

Let us consider both scenarios. Dr. Albers and Prof. Vahl run a small, specialized, closed ICU, which facilitates controlling the elective patient flow through their unit. At the same time, unexpected prolongation of ICU-stay in individual patients or a peak in emergency admissions makes such a unit vulnerable to fluctuations, unless the overall capacity is very generous (some “excess” of resources, as suggested by Prof. Van den Berghe) or patients can be discharged to other ICUs (to put it provocatively, outsourcing the problem). Small may be beautiful but vulnerable!

Prof. Van den Berghe runs a large multidisciplinary surgical ICU. Such a large unit profits from the fact that random fluctuations in a larger patient mix from different surgical specialties, including emergencies, tend to cancel each other out, and a larger personnel can be more efficiently allocated in treating patients with different severities of illness. Instead of having the probably somewhat smaller “excess” capacity necessary to cover the fluctuations in the large unit, Prof. Van den Berghe



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In my ICU,  
rescheduling elective surgery is  
considered to be a quality deviation,  
reflecting system failure.

and colleagues choose to (put provocatively, once again) outsource the “excess” capacity into emergency and recovery rooms, and in addition, to cancel elective surgery, when necessary.

Is an empty ICU bed really a financial problem? In a larger scale, I doubt it. Filling ICU beds in order to maximize charges may be attractive in some financing concepts, but it certainly increases health care costs. Flexibility of personnel allocation in work schedules is still possible despite the current tight work-time regulations. A higher number of beds is not expensive; the number of personnel needed to run them is. It is questionable, whether reducing ICU staff at the cost of

increasing staff and resources elsewhere, e.g. in the emergency and recovery areas for treatment of similar intensity, is likely to save costs or guarantee professional quality of care. In addition, operation room activities typically need more personnel per patient than the ICU. Unless the whole surgical team can be effectively put in to alternative production during the lack of ICU beds at very short notice, this may indeed represent the most expensive alternative.

In my ICU, rescheduling elective surgery is considered to be a quality deviation, reflecting system failure. Our 30-bed multidisciplinary (all specialties except major burns) ICU is the only ICU for adult patients in the 950-bed university hospital. Over 3000 patients are treated annually and over 1900 are mechanically ventilated. 40% of patients are admitted after elective surgery. In the last 5 years, rescheduling of elective surgery due to lack of ICU beds has practically disappeared. Less than 0.5% (i.e. clearly less than 10 cases) of elective surgery needs to be rescheduled, and emergency capacity without delay is sufficient for our referral area.

This is a result of process- and resource optimization throughout the patient care process:

- the length of stay has been substantially reduced;
- flexibility in personnel allocation has been introduced;
- in addition to the central, closed, multidisciplinary ICU, sufficient intermediate care capacity has been created in the most relevant ICU customer clinics (representing a cost effective alternative);
- and a close collaboration between the ICU and the intermediate care units, including support and consultations from the ICU, has been established.

I believe that the efforts of Dr. Albers and Prof. Vahl and Prof. Van den Berge, as well as our own efforts, all have the same principal goal: providing high-quality intensive care in a cost-effective and resource-conscious way for all patients who need it. However, I am also convinced that the health care providing industry still has a lot to learn about optimizing our core production process – producing health for the patients.

# An interview with Professor Hans Flaatten on management in intensive care

Researcher and head of intensive care at Haukeland University Hospital, Professor Hans Flaatten believes that two goals essential to quality intensive care are good intra- and inter-team cooperation and respect, and constantly implementing the latest research findings into intensive care guidelines and practice.

## Introduction

Professor Hans Flaatten has been the Medical Director of the Intensive Care Unit at Haukeland University Hospital since 1994. The hospital is one of the largest in Norway, with 1100 beds, 8500 employees and a budget of 680 million USD in 2003. With a background in anaesthesia and key interest in outcome research, Hans Flaatten implemented a database early on in his unit, which soon developed to support clinical and outcome research. Organization of the Norwegian Registry of Intensive Care has now been awarded to Professor Flaatten's unit. With 65 nurses, 6-7 senior physicians-intensivists and 10 beds, the unit has a turnover of 450 to 500 patients per year. The nurse to patient ratio is slightly higher than 1 to 1. The intensive care mortality rate is 20 to 25% and the hospital mortality rate is around 30%. Professor Flaatten believes that two goals essential to quality care are good intra- and interteam cooperation and respect, and constantly implementing the latest research findings to intensive care guidelines and practice. His research resulting in a 25% reduction in ventilator time was the direct result of promoting nursing intervention in sedation regimes.

## What are the main directives of your role?

Our unit has a medical director and nursing director. As the medical director, one of my main directives is to maintain medical standards to the highest achievable level, which means ensuring that all my consultants and trainees have the highest possible level of competence. We have many internal methods to help achieve this, such as the internal education program for new residents and our written pocket guide describing our preferred methods. These guidelines are discussed and agreed within the department and I am responsible for keeping them up-to-date according to national and international guidelines. Although the guidelines should be followed in principle, people are allowed to think for themselves. If guidelines are not followed, we discuss the reasons with whoever has been on duty, not to criticise, but to understand and learn from practice. The guidelines can also be accessed on line via any of the eight terminals available to personnel in the department. We also have detailed routines for the nurses, to help with equipment testing and use.

Another responsibility is communication with other departments. Intensive care is not an isolated phenomenon; we live together with the rest of the hospital and it's important to communicate well with all the major departments who deliver patients to us. There is always room for improvement and I would like to have stronger links with other departments than we currently have.

We are responsible for the emergency team, for example for cardiac arrests. If someone pushes the button, we have to respond day or night. The intensivists are also responsible for a separate 8-bed burns unit. This is the only one in Norway. Although organizationally it belongs to the department of plastic surgery, we are responsible for the patients and this regularly keeps two of our consultants occupied.

We are responsible for the initial response to push the buttons for alert in the event of a disaster. The intensivist in charge at the time is called to the emergency central, briefed on the situation and decides which of three levels of alert to action. We lead the hospital catastrophe team until the hospital directors and formal catastrophe team are present. This may only require 10 minutes, but during a holiday night time, it can take several hours, so our organization needs to be alert and react fast. This is a very important role for us.

Strategically, I have two main medical goals: appraising and implementing recent research into our own practices, to keep up with progress, and contributing our own findings to the intensive care society. We aim to be in the forefront of research in certain areas, to provide input to others.

We can appraise our own performance using the Norwegian registry of intensive care, which allows benchmarking and highlights outliers. For example, there is an ICU (not ours) with an average length of stay in intensive care of 15 days, whereas the average in Norway is 5. We can also use international standards, for example for mortality we use the SAPS II scoring system and compare with standard mortality. Although it's 11 years old, we have used the system from year to year, so we can compare against our previous performance.

From time to time we set our own new targets. We had a recent break-through in reducing ventilator time through changing attitudes to sedation practices. We



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used a new method for us, statistical process control, which has been used extensively in industry, and is now increasingly used in health care. We gave more responsibility to the nurses to follow up and implement changes in the sedation regime and achieved a 25% reduction in ventilator time (Brattebo et al. 2004).

### How would a typical day proceed?

We first meet with the whole surgical services department, of which we are a subsection, and then go to intensive care where the physician in training, who has been on call for intensive care, reports on the patients. At 0900 the surgeons, consultants, physicians, nursing director and nurses discuss each patient to outline what the major tasks are for the day. This may change when we see the patient, but we try to plan as much as possible. Nurses only join the meeting for the discussion of the patients they are managing; otherwise too many people are present. At 0930 we start the round, and we write on a blackboard which physicians and nurses are responsible for which patients, so that everyone can see this clearly. Rounds are documented and unless a procedure is necessary earlier, these are usually performed after lunch, for example central venous catheters, tracheotomies etc. X ray rounds are done at about 1330 and at 1500 we start reporting for the next team coming on duty. Working hours already implemented for 10-15 years in Norway are now being implemented elsewhere in Europe. Junior doctors in Norway work about 46 hours per week, which is considerably less than in many other parts of Europe. Our shifts are 0730 to 1600 and 1600 to 0800. For both shifts there is a small overlap for handover.

I try to alternate weeks of administrative and clinical work. I still find clinical work very rewarding and necessary for me to keep up my own standards. Direct patient contact takes the majority of my time during my clinical working weeks.

### Describe two extremes in your role

It's easy to find extremes in intensive care. For example, patients' ages range from a 3 month old child to an 85 year old adult. The most extreme challenge is terminating active treatment for a patient who you know is going to die, but still needing to find the optimism to fight 100% for the next patient's survival. To adjust from one situation to the other can be difficult. If we have enough staff, and we know that terminating active treatment will take several days, we try to let the physician in charge work on that task alone. Even with treatment withdrawal, there is still much we can do for the patient and relatives.

### What kind of training and support have you been given for these tasks?

I have no formal training in intensive care; I learnt by doing it. Training programs have therefore become one of my major tasks. Newcomers should not have to learn on the job; they need a structured education. We've set up a 2 year training program in Scandinavia for intensivists, with annual intakes.

I've always been interested in research and this has helped me structure knowledge for myself. One of the first things I did as director was to create a clinical database to record data on activities, for documentation purposes internally, for hospital administration, and to create a platform for research. This strategic move (which has been constantly improved) now provides a comprehensive system with which to support follow up of patients and clinical research.

An essential need in intensive care is the implementation of medical therapies which have been shown to be of value to patients. This may seem simple, but very often even the original researchers themselves have difficulty applying their own findings to all of their patients, even with the knowledge that this would save lives. We need to implement the best possible standards. This is really an essential role as a medical intensive care manager.

Personal relationships are also very important; mutual respect and cooperation amongst colleagues. Nurses and doctors should be treated equally. Although their tasks differ, both are essential to intensive care. In fact, there are few places where doctors and nurses need to work so closely together.

Good cooperation within the group and between groups and keeping up with the best medical standards are two fundamental goals.

### What is the hardest decision you've had to make as an ICU Manager?

I still find it very hard when there is nothing more we can do for a child, and we have to communicate this to the parents. I often have children in intensive care the same age as my own, and at these times I feel emotional. Realising that we have nothing more to offer a child towards survival is a very tough time. It never gets better. It's a tough burden.

### What has been the most satisfying experience as an ICU Manager?

Our intensive care unit has developed from being a normal standard unit to probably one of the best performing in Norway.

In our area of outcome research, we equal many centres



in Europe. This is difficult to measure, although based on the number of abstracts from Norwegian units to ESICM, we are happy to have had the highest number accepted for the last five to six years. In 2004 there were six or seven abstracts from Norway and four of these were from our unit. Measured in this way, we have been successful in having an impact on the European society of intensive care.

Regarding clinical standards, I think we are also very high, but this is harder to prove, of course, because the case mix is very different from hospital to hospital and crude mortality rate should never be used as an outcome measure by itself. We're also extremely fortunate that our equipment is regularly updated.

We recently founded a Norwegian registry of intensive care. It is important to collect high quality data to be able to monitor the impact of Norwegian intensive care for new research. It's a good way to document whether there are deficits, for example in the number of available beds in Norway, which is low compared with European standards. We have had the registry for two years, but funding has only been awarded this year. The registry has now been allocated for organization from my ICU and I'm very proud of that.

Globally, in intensive care, I think we need to know more about differences, for example in standards and economics of intensive care in Europe. David Edbrooke's team (Edbrooke et al. 2004) is doing good work in this area, but it's difficult to get good quality data. We published a study (Flaatten et al. 2003) looking at costs in different settings between 1997 and 1999. We researched expected survival years for patients who survived, based on publicly available statistics in Norway. Two years following intensive care, mortality is the same as in the normal Norwegian population. For survivors we could therefore estimate the group total for future years of survival and divide this by the expenditure. We calculated that the cost was 650 euros per year, which isn't very much. This is another way of looking at costs, no less relevant than looking at daily ICU costs, and provides an efficiency parameter. In Norway patients are tracked by their social security cards, and data is available to researchers, so this type of cost analysis based on survival predictions is straightforward.

### **What is your supporting infrastructure and who are your contacts in your work?**

We work with the hospital's radiology department, laboratory sciences, and surgeons, and I'm well supported by my anaesthesia partners. This infrastructure is very important to us.

We are very well supported by the hospital administration

regarding equipment, and we were also able to rebuild the unit in 2001-2. We need the support of the hospital administration because intensive care is expensive. We communicate continuously to justify expenditure and get the funding we need. It's very difficult because we can't plan intensive care. Patients just arrive.

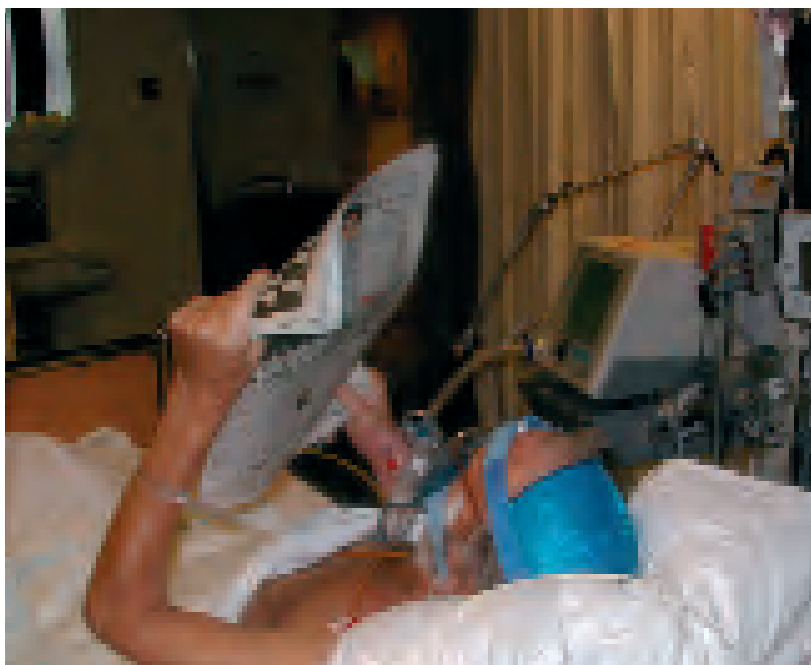
Legal claims are well supported by a government setup, which patients can use to apply for advice and compensation for malpractice. With this system, the issue is dealt with externally to the hospital, using consultants from other hospitals. We've only had one such experience in 10 years, but I act as a consultant in such cases for other hospitals.

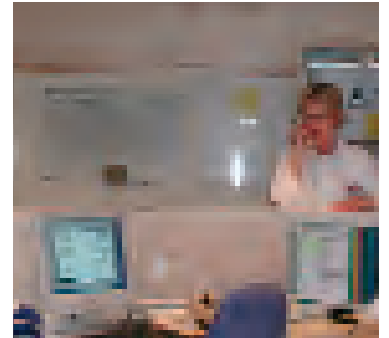
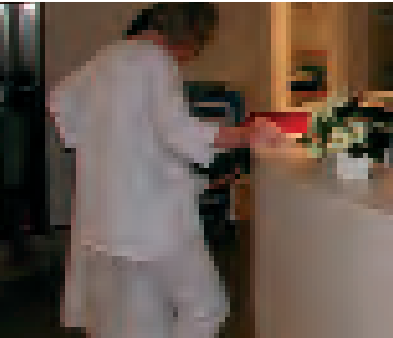
### **What sorts of medical/clinical management issues do you currently need to deal with?**

My priority is to have an outreach team. We lack evidence for this, but I believe the approach will save lives and resources. It's very logical. Once a patient has had a heart attack, there is little to be done. Records show that many patients deteriorate a couple of hours before an attack. A system to signal this as early as possible would be a very good thing.

I also want to have an on-line clinical management system that's able to interact from different sources (reference information and also in-house protocols) and guide treatment. For example, if you tried to prescribe nephro-toxic drugs for a patient who recently had elevated markers of bad renal function, the system would proactively alert on this, to avoid human error.

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We recently  
replaced all the  
monitors, not only  
in ICU but in the  
whole hospital.

### What sort of financial tasks are you dealing with?

Our financing is based on the work done in the previous year. The nursing director monitors finances and records what we have done and used. If the administrators request expense cuts, we demand that they also specify which patients should be refused treatment, those with 90% certainty of dying, or over a certain age, because we don't have waiting lists and or selective intake and the budget decision makers need to understand the difficulties. We only use 5% of the hospital budget in intensive care, whereas many European hospitals use 10%.

When equipment is old enough we replace it all at once. We recently replaced all the monitors, not only in ICU but in the whole hospital. We buy the same equipment from a single company. We have replaced 250 multi-monitors from the whole hospital, from all the operating theatres, post operative wards and intensive care. We are now in the process of changing all our ventilators which are nine to ten years old, and will buy 25 new versions of a particular type. We have done this with syringe pumps, ceiling mounted arms, infusion pumps, and other kinds of medical equipment.

Homogeneity in equipment has many advantages:

- Users are only exposed to a small number of equipment types;
- Learning how to use equipment is minimised;
- There is consistency in equipment for people working across different departments;
- Testing and maintenance and the expertise required are minimised for the medical technical department;
- Purchasing in bulk offers huge reductions in price.

We are the only hospital in Norway to have implemented this over the last 20 years. Old equipment which is still in good working order is recycled in hospitals with in Norway or to under developed countries.

### What personnel issues are you dealing with?

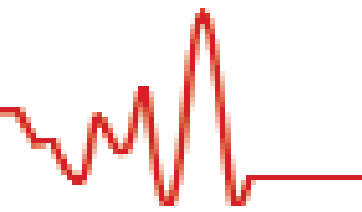
There are sometimes problems or conflicts to solve with the consultants, although with only six or seven, this is not so difficult. Training and education is the focus for the junior doctors. The nursing director manages issues amongst the nursing staff.

We don't receive many applications from elsewhere, so we tend to recruit from our large department of anaesthetists. Candidates are sent to the Scandinavian training program for intensivists, and we have internal training for doctors and nurses. On the nursing side, we always have a shortage of four to eight positions, which we are constantly trying to fill. We try to retain nursing staff through credit recognition, respect and by promoting professional development. 25 nurses from my department attended the ESICM Congress in Berlin last year. In Scandinavia, tasks that normally require a doctor's order elsewhere are more often delegated to nurses. Within a rational framework, nursing staff are given responsibility to wean a patient from a ventilator and extubate patients, depending on predefined criteria. Such delegation requires rational thinking and planning, but is very important.

I arrange the rotas for the consultants and 25 junior doctors. Special consultants rotate from the pain clinic to anaesthesia to outpatients. Nurse rotation is handled by the nursing director. Some protocols are designed by a working group and then I approve them; or I design them and circulate for review. I delegate representatives to research purchasing of ventilator equipment etc. All staff members understand their roles very clearly. Turnover of nursing staff is 10%, but we have a very stable team of physicians. We don't measure staff performance by individual. We measure our performance collectively by how the patients are doing.

**Thank you Professor Flaatten, for this insight into the management of your department.**

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)



# The French Healthcare System

The French healthcare system is one of the most advanced but also most expensive in Europe. A major review of the health system in 1996 introduced new regulations aimed at limiting the growth of health expenditure. These regulations led to much tighter government controls of public and private hospitals, as well as ambulatory care services, to rationalize the supply of health care.

The provision of French healthcare is based on:

- A national statutory health insurance system, linked to employment and financed by employers and employees
- An until recently, essentially total freedom of patients to choose and use private and public health services without referral

The almost universal (99% of the population) national system of compulsory health insurance (assurance-maladie) was introduced in France as far back as 1946. Health insurance is paid through different schemes following the occupation of the individual. The largest scheme, le régime général or national health scheme, accounts for some 80% of the population, covering employees, their families and pensioners from agriculture, trade and industry. Contributions to the scheme are made through payroll deductions, with 12.8% of gross salaries being paid by the employer and 6.8% by the employee. In addition to the statutory health scheme, over 85% of the population chooses to make additional voluntary payments into supplementary sickness funds (mutuelles) or private insurance schemes to cover charges and services not reimbursable under the national scheme. It is nevertheless, interesting to note (from figures reported in 1993), that despite the various health insurances, as much as 19% of total national health expenditure was still being paid by the patient, one of the highest shares in Europe (WHO Highlights on Health in France, www.who.org).

Traditionally, patients have the freedom to choose from both private and public health services and to consult with any doctor or specialist at any time without referral. GPs provide a great share of the primary health care

services (ambulatory care and house calls) and are paid on a fee-for-service basis usually according to a negotiated fee schedule although some doctors (30%) choose to set their own fees. Patients initially pay in full for their treatment and are later reimbursed by their insurance. The level of reimbursement follows a cost-sharing agreement with the insurance companies (ticket modérateur) and depends on the service provided and the needs of the patient: figures reported in 2002 indicate that a simple consultation is reimbursed at a rate of 70% (Bulletin d'Information de la Mutualité Sociale Agricole, No. 26, Aug-Sep 2002). Severely ill patients are exempt from personal contributions.

**Table: healthcare data sourced from WHO website**

| Indicator                            | Year | Value      |
|--------------------------------------|------|------------|
| Mid-year population                  | 2003 | 60,144,000 |
| Life expectancy at birth, in years   | 2000 | 79.35      |
| Physicians per 100,000 population    | 2003 | 334.86     |
| Nurses per 100,000 population        | 2000 | 674.55     |
| Hospital beds per 100,000 population | 2002 | 780.11     |
| In-patient care admissions per 100   | 1999 | 23.04      |

In principle, hospital care, both public and private, is paid for in a similar way with the patient paying the provider directly and seeking reimbursement from the insurance later. However, since the introduction in 1996 of a new system (tiers payant) whereby the hospital bills the insurance company directly, the patient in practice only pays the non-reimbursable sum (forfait hospitalier). With 1000 public hospitals, 750 private hospitals with a public utility function and 1400 private clinics under the Quantified National Objective (OQN), 13.5M hospitalizations were handled in the year 2000 (sourced from the French Ministry of Health).

An element of the modern computerized health system in France is the 'smartcard', introduced in March 1999, for claims transmission and reimbursement. The Vitale smartcard is a plastic card, carried by the insured, containing all relevant information about the person (name, social security number, date of birth, details on rights and benefits ...).

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)

# Structure, organization and practice of critical care medicine in France

Drs Bollaert and Martin summarise the restructuring of the intensive care infrastructure and training in France.

## Regulatory organization of critical care medicine in France

For over 30 years, health care establishments have provided themselves with a structural framework of critical care services. It became readily apparent to professionals that although designated under the heading of critical care units, there was an underlying heterogeneity with regard to their purpose, composition, and the quality of service provided. As with other high-risk medical activities, it thus became necessary to regulate critical care activities.

A first attempt in this regulatory restructuring was brought about by the publication of DGS Circular no 280 dated February 7th 1989, which indeed failed to significantly alter the existing landscape of critical care services. Hence there was a need to issue more constraining regulatory measures. Thirteen years later, Ministerial Decrees 2002-465 (5/4/2002) and 2002-466 (5/4/2002) were published. These decrees allowed to distinguish 1) critical care, intended for patients presenting or at risk of presenting acute multi-organ failure, 2) specialised intensive care, intended at managing patients presenting or susceptible of presenting acute failure of a particular organ under treatment by a given specialty, and 3) intermediate care, aimed at managing patients requiring recurrent and systematic clinical monitoring due to the severity of their condition or applied treatment. These decrees require that all critical care activities be administered in units specifically designed for this purpose, comprised of a minimum of 8 beds and contingent to approval.

The operational standards defined by these decrees can be summarized as follows: exclusive continuous medical care ensured by at least one member of the medical team, regulatory qualification standards for the medical staff, paramedical staff exclusive to the unit comprising of a least 2 nurses for every 5 patients and 1 assistant-care provider for every 4 patients, availability of a physiotherapist, psychologist or psychiatrist and biomedical trained personnel. Finally, minimal architectural as well as medical-technical environment standards are established. On-call duty, an integral component of full-time care, is obligatory and ensured by a member of the medical team.

A review of regional medical organization guidelines is necessitated by the publication of these new dispositions. It can therefore be surmised that this current

phase is one of transition, in which critical care structures which are compliant to the regulatory standards of these decrees now co-exist with other units which are not, either because their true activity is more closely related to intermediate care or specialised intensive care, rather than genuine critical care activity as defined statutorily, or because of insufficient available resources.

## Structural framework and critical care practice in France

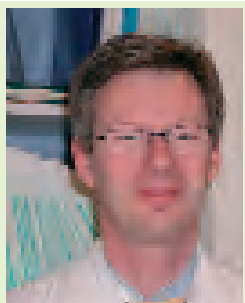
### NUMBERS AND DISTRIBUTION

According to official headings, approximately 700 to 1000 units are listed in France. This "self-declaratory" definition does not correspond to a certain number of instances in real-life practice. Schematically, we can safely say that all University-affiliated hospitals are equipped with at least one critical care facility, and that a majority of these institutions are equipped with a medical critical care facility and a surgical critical care facility. It is also in these latter hospitals where the majority of paediatric critical care services as well as cardiac and neurosurgical critical care facilities are found. Most of the larger general hospital centres have a medical surgical critical care facility. Critical care units in smaller-sized hospitals are often in fact medical or medical surgical intermediate care units. Some of these practice occasional life-support measures to a relatively limited number of patients. The existence of critical care units in private establishments are subject to the same size-related distribution patterns as depicted for public establishments.

According to a survey conducted in 2003, the average ratio of critical care beds is about 8/100,000 inhabitants with ranges from 5/100,000 to 12/100,000 from one region to another. The average number of beds in Critical care units of University-affiliated hospitals is 16, and for non-teaching hospitals 12.

### PERSONNEL

Medical staffing is established at an average 4.3 full-time equivalents per unit, a figure relatively identical for both University-affiliated and non-teaching hospitals. Conversely, University-affiliated hospitals boast on average three times more interns than non-teaching hospitals. Nevertheless, these numbers are fairly lower than the estimated overall national needs established consensually by unions and learned societies: 6-7 full-time



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equivalents for a 10- to 12-bed unit. These figures take into account recent national restructuring measures, including reduction in workload and establishment of mandatory rest periods.

According to a survey conducted in 2001, French intensivists had an average workload of approximately 70 hours per week, with considerable differences according to professional status (young doctors training in the specialty having the highest workload). Over 50% of physicians are over 45 years of age. Health care activities account for two-thirds of the workload of which 40% represent on-call duty schedules. The remaining one-third is spent on administrative and organizational activities, continuing education and research. In spite of their heavy clinical workload, many French intensivists are very actively involved in activities such as evaluation, audit and improving quality of care.

The majority of physicians practicing medical critical care are certified in “critical care” by the Order of Physicians, whereas physicians practicing surgical critical care are qualified specialists or skilled in “anaesthesia and critical care” or in “anaesthesiology and surgical critical care”. In medical-surgical units, their distribution is usually evenly mixed. A certain number of physicians who are not certified in one of these qualifications also practice critical care, often on a transitory basis.

The number of paramedical personnel is considered to be insufficient in the majority of hospitals i.e. in two out of three critical care units, with regard to the standards issued by the decree. Considering the reduction in workload and the foreseeable number of critical care units in France, it is likely that the regulatory standardization of this sector will only be partially achieved by the legislative deadline of April 2007.

## Training of critical care physicians

### OVERVIEW

Current training of critical care physicians in France falls under two distinct, but not mutually exclusive, modalities of certification: the “Diplôme d’Études Spécialisées Complémentaires (DESC)” in Medical Critical Care and the “Diplôme d’Études Spécialisées (DES)” in Anaesthesia-Critical Care, with both programs only accessible until now to interns selected through competition. However, from this year the program is also accessible to 6th-year medical graduate students, who have successfully completed national

standard examinations, whereby their ranking allows them to choose a residency position in either Medical Specialities, Anaesthesia Critical Care or Surgery categories.

### DESC IN MEDICAL CRITICAL CARE

A Ministerial order of June 20th 2002 (JO n° 173 of 26th July 2002 pages 12804-12805) upgrading the former so-called “type 1” DESC program to a “type II” DESC program now enables the classification of Medical Critical Care into the category of specialized fields. This important development represents another step towards supra-specialization. Access to the DESC in Medical Critical Care is contingent on the successful completion of a DES degree. All of the DES certifications in medical specialties, the DES program in Anaesthesia Critical Care and the DES program in General Surgery allow aspiring candidates to apply to the DESC Medical Critical Care program. Successful completion of the DESC program requires the validation of six semesters.

In 2002-2003, from applicants for DESC in Medical Critical Care, 42.8% had previously completed a DES in Anaesthesia-Critical Care, 15.6% Pulmonology, 12.8% Cardiology, 10.4% Internal Medicine, 7.2 % Nephrology, 5.6% Paediatrics; the representation of other medical specialties was anecdotal.

### DES IN ANAESTHESIA - CRITICAL CARE

Concurrent to the transformation of the DESC in Medical Critical Care program from type I to type II, the DES in Anaesthesiology-Surgical Critical Care became the DES in Anaesthesiology-Critical Care and was increased to 5 years training (JO n° 173 of 26th July 2002 pages 12804-12805). This new framework allowed the further consolidation of critical care training. It is currently too early to evaluate with certainty the overall effect of increasing the DES program to 5 years on overall enrolment levels by interns in Anaesthesia and Critical Care going into to the DESC in the Medical Critical Care program.

### CONTINUING EDUCATION

Continuing education capabilities in critical care are sizeable and of excellent quality in France, stemming from learned societies (Société de Réanimation de Langue Française, Société Française d’Anesthésie-

Réanimation), Colleges and Universities. While participation of critical care physicians appears to be fairly assiduous, there are presently no available statistics as to the average time spent on this activity.

**Perspectives**

The regulatory standards defined by the two “Critical Care” decrees will be enforceable by April 2007. If the spirit of the provisions provided therein is respected, the number of critical care units in France will be reduced significantly. This will favour a greater number of intermediate care units and, to a lesser extent, specialized intensive care units. These changes are consistent with a general framework of hospital restructuring, likely aimed at concentrating health care services towards care units that are adequately distributed geographically, equipped with extensive resources and capable of ensuring a high level of sustained activity. Maintaining an “adjoining” intermediate care unit, acting as a possible, but not exclusive, portal to and from critical care units should fill the existing void between the more conven-

tional hospital sectors unsuited for managing precariously ill patients, whose condition is susceptible to rapid deterioration. Such intermediate care units should be compliantly staffed with medical and paramedical personnel and must develop close working relationships with other departments.

Other factors, not as directly concerned with quality of care, further attest to the inevitable nature of this restructuring process. They include the evolving medical status of public hospitals, the demographics of the specialty and lastly the introduction of activity-based fees. The first two are intricately connected insofar as the reduction of workload and institution of mandatory rest breaks should alleviate, in the short term, some of the strains of the specialty less and less accepted by the younger generations.

Finally, the institution of an “activity-based fee” system which is currently replacing the global government subsidization system will most likely have an important role in ultimately determining the size and even the existence of critical care units.

References are available on request: [editorial@icu-management.org](mailto:editorial@icu-management.org)

## French intensive care associations



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- the organization of scientific meetings, national congresses, consensus and expert meetings, etc;
- publication of the “French Annals of Anaesthesia and Intensive Care”;
- publication of studies: SFAR recommendations;
- awarding of grants and prizes, study and research scholarships, research contracts, etc;
- setting up of appropriate committees as required.

**Société de Réanimation de Langue Française**

This scientific society founded in 1971, currently comprises 1200 members and organizes various activities revolving around two main themes:

- professional training and post-graduate education;
- promotion of clinical research and assessment of intensive care activities in hospitals.

Through these two activities, SRLF together with all actors in the intensive care sector, pursues the fundamental goal of situating intensive care appropriately within the health system.

In order to function and operate efficiently, SRLF relies on a 12-member Board of Directors and on 9 working groups: the scientific committee, ethics committee, INSERM/SRLF liaison committee, “Réanimation” magazine editorial board, assessment committee, emergency medicine committee, epidemiology and clinical research committee.

**Société Française d’Anesthésie-Réanimation**

The aims of this state-approved Society have been to study, promote and teach anaesthesia and intensive care since 1991, and additionally since 1998 to promote safety in all procedures carried out by intensivists and anaesthetists. Activities of the Society include:

**WEBSITE**  
**SFAR**  
[www.sfar.org](http://www.sfar.org)

**SRLF**  
[www.srlf.org](http://www.srlf.org)

# The ESICM annual congress: linking Berlin to Amsterdam

Drs Moreno and Phelan review last year's ESICM Congress in Berlin and provide a flavour of the September Congress in Amsterdam.

Last year, the 17th ESICM Annual Congress of the European Society of Intensive Care Medicine (ESICM) took place at the ICC (International Congress Centre) in Berlin (Germany) from the 10th to the 13th of October. The congress was highly successful, very well attended (4315 participants) and continued the process of change and development introduced two years ago in Amsterdam.

In a good mixture of science and education, more than 300 people started the Congress on Saturday attending five Post-Graduate courses (Acute circulatory failure, End-of-Life, ICU management & Organization, Infection, Mechanical ventilation) organized by the ESICM sections. An additional two courses are organized by the Committee of Education and Training in collaboration with the Society of Critical Care Medicine (SCCM): The Fundamentals of Critical Care Support Course (FCCS) for instructors and a Disaster Management course which incorporates the SCCM's Fundamentals of Disaster Management (FDM) course for instructors. The full course has a special European flavour with experts with practical, "hands-on" experience of natural disasters and man-made catastrophes providing a reality feel to the course. This feature and the interactivity and the 'teaching to teach' dimension, to the FCCS course in particular, have been very well received.

Registrants from 74 countries (86% were medical doctors) confirms the sustained growth of interest in our Annual Congress. The traditional session formats (thematic sessions, round-tables, pro-con debates) were complemented by Competency based sessions (still completely full; although the room had been enlarged since 2003 it was still too small to accommodate all interested participants). The newly introduced daily sessions on "What I learned today" and "What I learned in the last two years" raised some interest, together with the sessions based on the new PACT Modules, which profiled newly published 'Hot off the Press' modules from the Society's distant learning programme for Intensive Care Medicine - PACT. Many of these sessions will be repeated in Amsterdam with new modules and with slight changes to allow more comprehensive content exploration and interaction.

The Education Track is patently an important continuing education and pre-EDIC component to the Congress which attracted a loyal attendance among a cohort of senior and Intensive Care trainee congress registrants. Work is required to ensure that the topics are more consistently attractive and to endeavour to have the modern educational devices e.g. the interactivity and potential of the digivote system utilised to the optimum.

Last but not the least, the opening session included a lecture given by Professor Lambert Thijs about the congress motto: "Intensive Care: A Science and an Art", that will certainly stay in the memory of all that took part in this unique moment. A summary of the lecture has been reproduced in a recent society newsletter.

This year, and for the third time since its creation, the European Society of Intensive Care Medicine (ESICM) will have the Annual Congress in the beautiful city of Amsterdam (The Netherlands) from the 25th to the 28th of September, under the motto "Facing the challenge: the ICU without walls".

The meeting will start on Saturday with a Post-Graduate Course addressing the multiple challenges of establishing an ICU without walls e.g. multidisciplinary education and training, integrate clinical care. Also, other Post-Graduate courses will take place on Saturday and Sunday (FCCS, FDM, Neuro-intensive care, Non-invasive mechanical ventilation and Severe sepsis and septic shock).

During the Congress, around 200 speakers will fulfil 650 commitments in the programme, some organized as joint-ventures with other Societies (e.g. SCCM, ESA, ESPEN, ESCMID and ATS). Several formats will be available to meet the needs of all professional groups, with special emphasis on medical doctors, Nurses & other Allied Health Professionals.

#### POST-GRADUATE COURSES

- The Congress Committee is organising 6 post-graduate courses that will be held on the Saturday and/or the Sunday prior to the core congress programme.

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#### CONTINUING PROFESSIONAL DEVELOPMENT SESSIONS

- The ESICM Education and Training Committee has

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set up, with the collaboration of the Division of Scientific Affairs, a full educational track (11 sessions) throughout the congress. An interactive format (computer digivote system) will be available. An encouraging new education feature which was piloted successfully at Berlin, in conjunction with established leaders in the area of Clinical Simulation, was the application of Simulation to Intensive Care scenarios. This feature was enthusiastically received by those who became involved in these workshops. There is a future potential to incorporate the PACT clinical challenges into Simulation scenarios, the demonstration of which may well be a feature of future Congresses.

PACT SESSIONS

- These sessions are based on newly published or newly updated PACT modules. An attraction is that the speakers are PACT authors and audience participation has been a strong feature.

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THEMATIC SESSIONS

- Lectures by key experts and well-known speakers on related topics. These are State-of-the-Art lectures scheduled from 8.30 till 09.30 and from 16.00 till 18.00 each day.
- They include conferences, round-tables, pro-con debates.

COMPETENCY TRAINING SESSIONS

- The ESICM Congress Committee organises for the second time 22 Competency training sessions. These sessions are 30-min training sessions on “How do I...?”. Speakers and chairpersons are outstanding experts in their field willing to share practical experience with physicians and nurses.

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PATIENT CHALLENGES SESSIONS

- Two key experts and well-known speakers interact based on a real clinical case. The case is progressively presented by the chairman and discussed by the speaker (with interaction with the audience). Competitive and alternative diagnostic and therapeutic options are discussed and evaluated.

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INDUSTRY SPONSORED SESSIONS

- Organized at lunch time by the industry, with two chairs (one from the company and the other from the ESICM).

Finally, we hope to have again more than 1000 abstracts presented as in Berlin. The presentation of these free abstracts, mostly during unopposed sessions, allows the interaction of young and senior intensivists from all over Europe and the world and continues to be

for us a matter of joy and pride, helping the mixing of science with clinical challenges, helping to build what we called two years ago in this same city “The Scientific Basis of Intensive Care Medicine”.

This material will be presented in two formats:

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ORAL PRESENTATIONS

- These sessions include the Oral presentation of 6 successive abstracts. Each presenter is allowed a 10-min presentation followed by a 5-min time slot for comments and discussion by the audience and the chairpersons.
- The afternoon sessions include a 15-min introduction lecture by an expert in the field, which should give an overview of the current State-of-the-Art on a specific aspect of the topic related to the abstracts presented in the session; and a 5-min conclusion during which the speaker will discuss current or future issues in the field covered by the abstracts presented.

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POSTER SESSIONS

- These sessions include a viewing and discussion of the posters on a related topic, from 11.10 till 13.00, during which the presenting authors stand beside their posters. There are two chairpersons for each session.

The awards for the best oral presentations and/or posters will be delivered on a daily basis, together with and this is something new – a special award for the best material derived from the European Critical Care Research network. The abstracts produced by this cooperative effort of the ESICM will also have a special display area, near the ESICM booth and will be on display during all of the congress.

In conclusion, Amsterdam will be a fine blending of science and education, of young and old people, of professionals with very different backgrounds and working medicine in very different environments, but united by the same challenge: to deliver in a humane manner the best possible care to the appropriate patient in the right time. Analyses of registrants demonstrate, peculiarly that a majority of attendees are not ESICM members. We suggest to the entire ESICM membership, of over 3,000 persons, that the new, evolving, comprehensive format covering new Science and Continuing Education in Intensive Care is extremely attractive and is especially inviting to all (as is the fine wine at the opening ceremony!). Members additionally enjoy favourable registration rates and a greater presence of members would undoubtedly enhance the congress further and help all to find the whole European Congress experience especially useful and most enjoyable.

See you in Amsterdam.



# Author Guidelines for ICU Management

## Content

Articles may focus on any management or practice issue in intensive care related to economics, quality of care or patient outcome. We only accept scientific papers with a clear connection to management and practice issues. We also invite Comments for publication, which are personal opinions of the author, and Letters to the Editor, which are published at the discretion of the Editors.

Submissions may not have been published previously or be currently submitted for publication elsewhere. Articles must be written by independent authorities and any sponsors for research named. If manufacturers are named in an article, the text must present an unbiased view, not supporting any particular company.

## Submission guidelines

Authors are responsible for all statements made in their work, including changes made by the editor and authorized by the submitting author.

The text should be provided as a word document via e-mail to [editorial@icu-management.org](mailto:editorial@icu-management.org). Please provide a contact e-mail address for correspondence.

Following review, a revised version, which includes the editors' comments and recommendations, is returned to the author (at the contact e-mail address) for authorization.

## Length

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

Comments: maximum 700 words

Letters to the editor: maximum 175 words

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

## Structure

Article texts must contain:

- a title;
- names of authors with abbreviations for the highest academic degree;
- affiliation: department and institution, city and country;
- main authors are requested to supply a portrait photo (see specifications below);
- a summary of one or two sentences (no more than 30 words) describing the content;
- one contact name for correspondence and an e-mail address which may be published with the article;
- website, if appropriate;
- acknowledgements of any connections with a company or financial sponsor;
- an abstract (optional), introduction, main text and summary/conclusion. The main text may also include sections with subheadings as appropriate;
- authors are encouraged to include checklists and/or guidelines which summarise findings or recommendations;
- references or sources, if appropriate, as specified below.

## Writing style

Articles must be written in English (with English spelling), with short sentences, a clear structure (see above) and without bias. Full stops in numbers may only be used to indicate a decimal place; otherwise use commas as separators.

## Images

Main authors are invited to supply a portrait photo for publication with their article. This and any other relevant images for publication with an article should be sent by e-mail as separate files (only high resolution images with 300dpi) and their order of placement in the article must be clearly indicated. Only the electronic formats ".tif" or ".jpeg" can be used. These need to be of quality "10" ("high"), with an original size no smaller than 9cm x 10cm. If an image has been published before, permission to reproduce the material must be obtained by the author from the copyright holder and the original source acknowledged in the text, e.g. "© 2004 Kirstie Edwards".

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Please use the Harvard reference system. Citations within the text for a single author reference should include the author surname and year of publication; for a citation with two authors include both author surnames and year of publication; for more than two authors, include the first author surname followed by "et al." and the year of publication. Multiple citations should be separated by a semicolon, and listed in alphabetical order.

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

The format for listing references in submitted articles should follow the Harvard reference system.

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

Readers will be provided with an e-mail contact for references, which will be kept on file and supplied on request.

Authors are responsible for the accuracy of the references they cite.

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

## Thank you

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## AGENDA

### APRIL

- 28-29** International Consensus Conference in Intensive Care Medicine  
Budapest, Hungary  
[www.ersnet.org/icc05](http://www.ersnet.org/icc05)

### MAY

- 26-28** IX National Congress on Intensive Care Medicine / International Symposium on Non-Invasive Ventilation  
Vilamoura, Portugal  
[www.spci.org/index2.htm](http://www.spci.org/index2.htm)
- 28-31** Euroanaesthesia 2005 Annual Meeting of the European Society of Anaesthesiology  
Vienna, Austria  
[www.optionsglobal.com/vienna/congress](http://www.optionsglobal.com/vienna/congress)

### JULY

- 15-17** 4th Summer Conference in Intensive Care  
New York, USA  
[www.sccm.org/education/summer\\_conference/index.asp](http://www.sccm.org/education/summer_conference/index.asp)

### AUGUST

- 27-31** 9th Congress of the World Federation of Societies of Intensive and Critical Care Medicine  
Buenos Aires, Argentina  
[www.sati.org.ar/newstyle/congresos/congreso/2005/index.htm](http://www.sati.org.ar/newstyle/congresos/congreso/2005/index.htm)

### SEPTEMBER

- 17-21** European Respiratory Society 15th Annual Congress  
Copenhagen, Denmark  
[www.ersnet.org/ers](http://www.ersnet.org/ers)
- 25-28** 18th Annual Congress European Society of Intensive Care Medicine / Facing the Challenge: Intensive Care without Walls  
Amsterdam, The Netherlands  
[www.esicm.org](http://www.esicm.org)

### NOVEMBER

- 10-12** 2nd Congress of the European Federation of the Critical Care Nursing Association  
Amsterdam, The Netherlands  
[www.efccna.org/congress2005.htm](http://www.efccna.org/congress2005.htm)

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