ICU MANAGEMENT

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Outreach Care

Comparison charts: PCA infusion pumps
Process quality control
Intensive care in Austria

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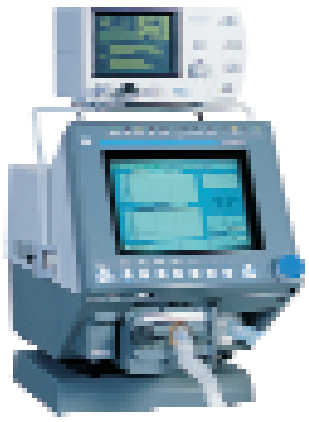

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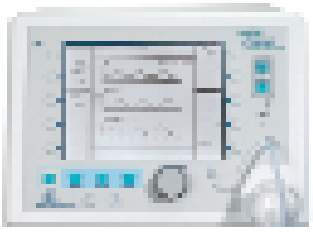

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Sharing **solutions** in management

Growing and changing needs in intensive care require innovative and varied solutions. In this issue, we cover some of these solutions, from proposed legislation aimed to encourage trials for paediatric medicines, to the application of industry-based process control techniques to intensive care management. Solutions are increasingly to be found across disciplines and through **ICU Management**, we aim to communicate across as many different specialties related to intensive care as possible.

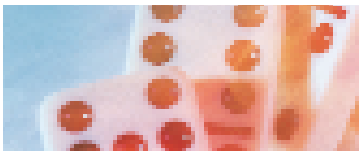
Karel Allegaert and colleagues address the use of off-label or unlicensed drugs in neonates and children by illustrating the potential and feasibility of pharmacokinetic studies in neonates in intensive care. At a European level, Helicia Herman explains the key objectives of a proposed regulation on medicines intended for paediatric use.

Proposed legislation at a national level is focussed in Professor Lemaire's article on the new end of life law in France. This law on withdrawal of life support in terminally ill patients should help to provide legal protection for physicians managing such situations, and Professor Lemaire draws some interesting comparisons between European and North American practices and attitudes to this issue.

Health services in Australia and the UK appear to have similar attitudes in their receptiveness to the concept of outreach. Ken Hillman and I debated the pros and cons of the need for outreach teams at the International Symposium of Intensive Care and Emergency Medicine (ISICEM) this year, and indeed we will progress with that debate in a later issue of **ICU Management**. First though in this issue, Ken gives his account of the evolution of outreach and development of the Medical Emergency Team. A crucial concept underpinning the rationale for outreach teams is that abnormal physiological values observed on the ward can be identified for early intervention, a topic on which Dr David Goldhill writes. Although practiced for some years now, implementation of the concept of outreach has not been completely straightforward, as explained by Nancy Santiano and colleagues.

A continuum of care emerges with new concepts such as outreach, from ward level care to high dependency care in the ICU. Intermediate level care, nearer the ICU end of the continuum, may offer a solution to the mismatch between ICU demand and supply. In our Points of View section, Professor Burchardi gives his personal perspective and describes some of the advantages and difficulties of step down beds in a mixed model unit, and how he sees management of such resources in the future.

In our last issue, Drs Poelaert and Schüpfer discussed organizational strategies to maintain and improve quality of care and cost containment with blood gas analyzers. In this issue, Kees Polderman and Armand Girbes present the clinical arguments for on-site analysis. Manu Malbrain explains how remifentanil may lead to improved clinical outcomes, and with infusion pumps under the spotlight in our product comparison charts, Andrea Casati and colleagues review the management of regional analgesia in trauma and post-surgical patients in the ICU.



In addition to these clinical management issues, Professor Hiesmayr from Vienna introduces us to a new way of managing processes in intensive care. He and Professor Schmidlin show how statistical methods already well established in industry can be adapted to monitor process in the intensive care unit. Professor Marko Noc gives us an insight into his management of the Centre for Intensive Internal Medicine at the largest tertiary hospital in Slovenia. Dr Noc describes some interesting approaches to decision making, recruitment and personnel management, which may be of interest to other heads of intensive care departments. Following the recent study by Professor Van den Berghe and colleagues on glucose control using intensive insulin therapy, Professor Jan Wernerman presents a critical review of the limited evidence to guide nutrition management for ICU patients.

Finally, we review and preview major gatherings, which are so essential to progressing the debate and sharing new knowledge and experience. In this issue, I present a review of management issues covered at ISICEM held in Brussels in March. Dr Andrew Rhodes, Chairman of the Cardiovascular Section of the European Society of Intensive Care Medicine (ESICM) previews ESICM's annual Congress to be held in Amsterdam in September, and Dr Gordon Drummond previews Euroanaesthesia, the Annual Scientific Meeting of the European Society of Anaesthesiology (ESA), to be held in Vienna in May.

It is this last meeting which has prompted us to focus on intensive care in Austria in this issue. Professor Alfons Hammerle introduces us to the trends in general health care and Dr Peter Krafft from the Austrian Society of Anaesthesiology, Resuscitation and Intensive Care Medicine, describes the current status of postoperative intensive care medicine in Austria.

So with this collation of communications on management from such eminent experts from different specialties related to intensive care, we hope there is some new knowledge to help with management in your ICU.

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European Commission proposal on **medicines for children**: enough **incentives** for **industry**?

The proposal for a regulation on medicinal products intended for paediatric use (http://dg3.eudra.org) adopted by the Commission in September 2004, is designed to increase the availability of medicines tested specifically for children. This article describes the key measures proposed (table 1).

In detail

A new EMEA committee, with expertise in all aspects of the research, development, authorisation and use of medicines for children is central to the proposal and its operation. The committee will be responsible for the assessment and agreement of paediatric investigation plans and requests for waivers and deferrals. The proposal aims to integrate the development of medicines for children as an integral part of the development program for adults. To offer industry an incentive and reward for these studies, an extension of 6 months to the supplementary protection certificate has been foreseen. Secondly the proposal provides for the creation of a Paediatric Use Marketing Authorisation (PUMA) to establish a vehicle for providing incentives for off-patent medicines. A PUMA will utilise existing marketing authorisation procedures, but is specifically for medicinal products developed exclusively for use in children. PUMA applications will require data necessary to establish safety, quality and efficacy specifically in children, including any data needed to support an appropriate strength, pharmaceutical form or route of administration of the product, collected in accordance with an agreed paediatric investigation plan.

More clinical trials: will children be at risk?

Although there may be concerns about trials in the paediatric population, there are also concerns about giving medicines to a population in which they have not been tested. The new EU Directive on clinical trials (see also ICU Management issue 1/2005 p6-8) lays down specific requirements to protect children who take part in clinical trials in the EU. The public health threat from daily use across the EU of untested medicines in children can therefore be safely addressed through the study of medicines for children, controlled and monitored through the existing EU Directive.

Are the incentives foreseen sufficient?

The provision of the patent extension of six months reflects incentives legislated in the USA. However, is this the best way forward in Europe? In the EU, there is already a system in place to provide incentive for the development of less lucrative medicines for small populations, in the form of the Orphan Medicinal Product Regulation. The Committee of Orphan Medicinal Products at the EMEA has, in the four years during which it has been operational, received more than 305 applications and authorised more than 178 orphan medicinal products, including many for paediatric indications. This demonstrates the success of the existing provisions (Mc Clay 2004).

The responsible rapporteur at the European Parliament, Dr Peter Liese, believes that:

- the proposal should be improved with regards to the provisions concerning the out-of-patent drugs and academic research;
- the extension of market exclusivity for a longer period means that generics will enter the market later, and
- firms who do research may criticize the enforcing part of the Commission's proposal, since it obliges them to carry out additional work.

Another problem seems to be that for many life-saving medicaments the patent and data protections have already expired, so that extending market exclusivity for six months is no longer possible. According to Dr Liese, a solution would be the mobilisation of sufficient financial support. Another option would be obliging the pharmaceutical industry to finance trials on medicaments that no longer have patent or data protection. Despite these reservations, Dr. Liese (2005) has expressed the Parliament´s willingness to adopt the regulation quickly.

Table 1: Key measures of the proposal

- setting up a new expert committee within the European Medicines Agency (EMEA)
- the requirement for data on the use of the medicine in children at the time of application for marketing authorisation
- a reward for studying medicines for children in the form of a six-month patent extension
- an award of ten years of data protection for new studies for off-patent medicines via a Paediatric Use Marketing Authorisation (PUMA)
- increased safety monitoring for children's medicines and compulsory submission by industry of existing studies in children
- an EU inventory of the therapeutic needs of children and an EU network of investigators and trial centres to conduct the studies required
- a system to provide free scientific advice for the industry

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Maquet

Every year, Frost & Sullivan presents a Market Leadership Award to a company that has exhibited market share leadership through the implementation of market engineering strategy. Following their recent "Strategic Analysis of the World Mechanical Ventilators Market", Frost & Sullivan have selected MAQUET Critical Care as the recipient of the "2005 Market Leadership Award" in the global ventilators market. MAQUET's SERVO-i ventilator platform allows for a complete spectrum of treatment strategies for all patient types, conditions and care areas.

Nils Rosén, Vice President Marketing and Christian Keller, President, MAQUET Critical Care holding the 2005 Market Leadership Award

Roche

A recent study (Menendez-Jandula et al. 2005) has shown that patient self-management with the CoaguChek S system from Roche Diagnostics, reduces the risk of major complications and minor haemorrhages by up to 70% and the event of mortality by up to 60%. This was demonstrated in a single centre study comparing self-management of oral anticoagulant therapy with clinic management. Self-testing with the CoaguChek S system gives patients information about their level of anticoagulation and allows them to adjust the doses of medication if necessary. The major complication rate was 7.3% in the conventional management group and 2.2% in the self-management group, which corresponds to a risk reduction of 69.8%. The authors of the study estimate that at least 50% of patients on anticoagulant therapy could safely use patient self-management to monitor their treatment.

ESICM poster awards

Award-winning posters for research in management

At the 2004 annual Congress of the European Society of Intensive Care in Berlin, three of the nine award-winning posters were related to research in intensive care management, for work in Denmark, France and Belgium. Summarised briefly here, full abstracts from these posters are available in the Official Journal of the European Society of Intensive Care Medicine.

Aarhus University Hospital Denmark

Dr Pedersen and colleagues from Aarhus University Hospital in Denmark evaluated the precision of their triage protocol (American College of Surgeons 1999) for identifying severely injured patients with an Injury Severity Score > 15. Triage criteria were prospectively collected for 6 months. Out of a total of 15,162 patients attending the emergency department, 242 were admitted primarily as trauma patients, of which 54 were severely injured. Sensitivity was 92%, undertriage 8%, specificity 76%, overtriage 24%, and positive predictive value 22%. Although the results were within the recommendations of the ACS, the positive predictive value was only 22%. Mechanism-of-injury was the only criterion associated with overtriage. The results are being used at Aarhus to inform on the trauma triage criteria.

Saint Joseph Hospital Medical-Surgical ICU Paris, France

Dr Garrouste-Orgeas and colleagues researched ICU admission procedures in patients over 80 years old and the outcome one year following the triage decision in terms of autonomy and quality of life in a single centre prospective study. Admission was requested for 180 patients, of whom 26.6% were admitted. Factors significantly associated with refusal in a univariate analysis were age, McCabe score, Katz's Activity of Daily Living score, whether the patient was living in an institution, physician ICU experience and bed availability. From multivariate analysis, factors associated with ICU refusal were medical status, age > 85, normal toileting ability, examination by the triaging physician and lack of bed availability. The hospital mortality rates for the admitted, too sick to benefit and too well to benefit were 62.5% (ICU mortality: 50%), 70.8%, 17.6% respectively. Hospital mortality was high irrespective of reason of refusal. Reduced quality of life reported by the patients suggests that physicians should discuss patient's or surrogate preferences about ICU admission.

Scientific Institute of Public Health, Brussels, Belgium

Dr Morales and colleagues won the 2000 Euro poster award from ESICM 2004 for their work on the assessment of ICU-acquired infections surveillance. Their study aimed to evaluate data quality of the Belgian national surveillance of ICU-acquired pneumonia (PN) and bacteraemia (BAC) and to assess factors influencing surveillance performance, such as workload or the intensivist's role. Sensitivity was 60.9 % for BAC and 53.7% for PN, and specificity was 99.4% for BAC and 98.5% for PN. Decisions to participate in the surveillance taken outside the ICU without involvement of the intensivist, reduced the quality of reported data by 6-fold. Participating / refusing units did not differ significantly. These preliminary results suggest good surveillance specificity, a need to improve sensitivity and that intensivist involvement raises data quality.

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The **future** of intensive care medicine: facing a **physician shortage**

ISICEM hosted an exchange of scientific innovations, both historical and futuristic. Predicted physician shortages need innovative solutions; some more traditional and some exploiting the most advanced technology available.

This year the International Symposium of Intensive Care and Emergency Medicine celebrated its 25th anniversary, providing a special opportunity to look back over the past 25 years of intensive care medicine and forward to the next 25 years. Intensive care medicine has seen many changes since its early development following the polio epidemic of the 1950s. Technological and clinical advances have changed the face of all aspects of patient care, including diagnosis, monitoring and patient management. Intensive care medicine has developed into a specialty in its own right, with trained 'intensivists' working with a unique set of skills to care for the critically ill patient.

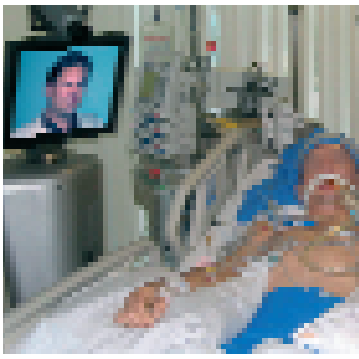
But, what does the future hold? Undoubtedly as our understanding of disease process increases, we will add new therapeutic interventions to our armamentarium and improve outcomes for our patients. Genomic and proteomic techniques will help model critical illness and target therapies to groups of patients most likely to benefit. Improved monitoring systems and markers will provide ongoing information on the effectiveness of therapies, enabling therapeutic interventions to be titrated according to response. Better study and understanding of the importance of quality of life and the long-term effects of intensive care treatment will improve patient care. These and other exciting aspects of intensive care of the future were covered in several sessions.

However, while these provide interesting images of the future of intensive care medicine, there are considerable concerns about who will be around to deliver this care. This was a keen topic of discussion and debate during the Symposium this year. The need for intensive care will increase significantly as the population ages and people survive conditions that they would previously have succumbed to. The corresponding increase in ICU physicians, however, will be minor. The Committee on Manpower for Pulmonary and Critical Care Societies published a study in 2000 predicting that the demand for ICU services will increase by 66% by 2030 (Angus et al. 2000). Extrapolating current rates of supply of intensivists, the predicted shortfall in intensivist hours will be 35% in 2030.

Intensivists are essential to good ICU outcomes and their presence has been shown in numerous studies to reduce ICU mortality, shorten ICU stays and duration of mechanical ventilation and to reduce requests for arterial blood gases, etc. (Vincent 2000). Indeed, the Leapfrog Group, a US business consortium of more than 150 private and public health care sector purchasers, now requires hospitals within its health network to have board-certified critical care specialists available on and exclusive to their ICUs during daytime hours. At other times specialists should to be able to return to the ICU, or arrange for an on-site physician to do so, within 5 minutes of being paged. This group estimates that applying such standards could save more than 54,000 lives in the US each year (http://www.leapfrog-group.org/media/file/Leapfrog-Birkmeyer.pdf). But again, how can we supply ICUs with all these dedicated staff, with a predicted shortfall already of 35%!

Several possible approaches were discussed during the Symposium. First, and perhaps the most simple, is that we need to make the specialty attractive so that young doctors will want to specialize in the field, and specialized doctors will want to stay. Second, with regionalization of intensive care services, as already achieved with neonatal ICUs, patients would be cared for in larger, but fewer units facilitating the provision of adequate intensivist cover. Third, telemedicine could be employed to ensure at least some form of intensivist cover for smaller ICUs lacking sufficient numbers of these specialists. Using such technology (figure 1), intensivists can perform virtual rounds as often as required on distant patients with access to current patient data and monitoring systems.

Implementation of such a program has been shown to be associated with reduced ICU and hospital mortality, shortened ICU stays and improved financial performance (Breslow et al. 2004). While further study is needed to confirm these findings, being able to manage several ICUs from one place, using telemedicine and robots, could provide a way of limiting the impact of the huge gap between supply and demand that is forecast for intensive care medicine, and is already beginning to be felt. Health care managers and policy makers need to take steps now to increase the supply of physicians trained in intensive care medicine and to explore how best to employ those who are available.



© "InTouch Health Inc., Mission Hospital"

Figure 1: Dr. John Shaver uses the RP-6™ Robot to check in on his patient in the ICU at Mission Hospital from his office located several miles away.

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History of outreach

Ken Hillman describes the evolutions in health care which have led to the development of hospital wide preventive patient-centred care for seriously ill patients.

The history of hospitals

The word "outreach" is being increasingly used to describe care of the seriously ill or potentially seriously ill by specialists in Intensive Care Units (ICUs). The term "outreach" in itself is significant as it moves from defining the seriously ill in geographical terms within high dependency environments to defining them in terms of patient characteristics. It is a move away from treating patients according to man-made silos, so characteristic of hospital care, to a patient centred one. The concept appears so sound that it is hard to believe that it should be any other way. In order to understand why it has taken medicine so long to establish a system around patient needs rather than according to artificial constructs, we need to explore the history of how hospitals came to function as they do and how that led to increasing numbers of potentially preventable deaths and serious complications.

Hospitals have their roots in Christian monasteries in medieval Europe (Porter 1979). Initially they were small and mainly for pilgrims. This was followed by the great age of hospital building which coincided with the first universities such as in Bologna (1158) or Oxford (1167). Medical facilities were soon established within these universities and the hospitals became the centre of medical education and research. This largely remains the case today; hospitals being the self-proclaimed flagships of medicine.

Hospitals, especially the larger ones were where teaching and research was carried out. Until approximately the middle of the 20th century they were mainly for the poor; the name "hospital" was associated with death, pestilence and insanity (Porter 1979). Professional nursing and antisepsis changed the reputation of hospitals.

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Islands of care

Hospitals still largely consist of islands of territory based on centuries of tradition (Hillman 1999; Hillman et al. in press). Senior doctors "own" patients, supported by their own junior medical and nursing staff. Individual wards are supervised by a senior nurse, supported by more junior nurses and ancillaries. Operating theatres (OT), diagnostic suites and emergency departments (ED) are separate and distinct departments. All these geographical sites in a hospital interact with each other, but largely on their own terms.

Medical training itself does not lend itself to management of at-risk patients who fall outside the specific expertise of the supervising specialist. There is little in the way of undergraduate education in resuscitation and critical care medicine (Harrison et al. 1999). After graduation, doctors usually spend 1-3 years gaining experience in hospitals. However, they may not be exposed to formal training in the increasingly complex area of resuscitation. Moreover, medical specialisation is increasing (Donini-Lenhoff and Hedrick 2000), reducing a trainee's experience and resulting in limited skills of specialists in managing acute illnesses involving several interacting organs (Chantler 1999; Grumbach 1999), and sometimes non-existent skills in resuscitation (Thwaites et al. 1992).

At the same time the hospital patient population is changing. The general population is aging (UN Secretariat 1998) with changing disease demographics and increasing co-morbidities (van Weel and Michels 1997). Combined with pressure to decrease hospital length of stay and streamline care, hospitals increasingly care for patients who are often seriously ill with complex conditions, even on the general wards.

These factors combine to make hospitalised patients vulnerable to deterioration. In summary, the factors include: disjointed islands of care; doctors not adequately trained in acute medicine and resuscitation; nurses who record and observe deteriorating patients, but are not engaged with an appropriate response system; and a population of patients who are often old with multiple co-morbidities. These factors are seen in the light of increasingly complex surgery and procedures, as well as patients receiving powerful drugs with potentially serious side-effects.

Potentially avoidable deaths and serious complications

It is not surprising that in an environment where there is little in the way of a patient centred system that operates across the usual hospital islands of care, that there is a large number of potentially avoidable deaths (Brennan et al. 1991; Leape et al. 1991; Wilson et al. 1995). Studies show that for up to 50% of patients, who are not designated as "not for resuscitation" (NFR), severe disturbances of vital signs are documented in the clinical notes. In this group there was no appropriate response in the 24 hours before death (Hillman et al. 2001; Goldhill and McNarry 2004).

The same potentially preventable antecedents were noted to occur before other serious adverse events such

as cardiac arrests (Hodgetts et al. 2002; Schein et al. 1990) and unplanned admissions to the Intensive Care Unit (ICU) (Goldhill et al. 1999; Hillman et al. 2002; McQuillan et al. 1998).

Factors noted to be associated with the failure to recognise and institute an early response to these serious antecedents include a lack of organisation, lack of knowledge of what constitutes a seriously ill patient and lack of supervision of junior medical and nursing staff (Goldhill et al. 1999; McQuillan et al. 1998).

These factors may also help to explain the failure of interventions in patients admitted to an ICU late in the course of their illness. There were many studies in the 1980s and 1990s evaluating goal directed therapy in patients admitted to an ICU, where supranormal levels of oxygen were delivered according to protocols. After initially promising results, larger studies demonstrated that this approach had no beneficial effect on patient outcome (Gattinoni et al. 1995; Hayes et al. 1994; Hinds and Watson 1995). Interestingly, patients in these studies were seen as either responders or non-responders in both the intervention or control groups. This observation is probably related to the extent of organ damage before resuscitation attempts were commenced.

Systems for managing the seriously ill in acute hospitals

Currently patients who are critically ill are managed in specialised areas. They are initially managed in the ED. During and immediately after surgery, they are managed in the OT complexes with appropriate monitoring and by specialised staff. More seriously ill patients are managed in intensive care or high dependency environments. The latter may be of a general nature or specialised, such as in neurosurgical or cardiothoracic units.

As described previously, the patients most at-risk in general hospitals are not those in specialised units, but those on general wards where lack of monitoring and awareness concerning serious illness, combined with inappropriate or delayed responses, can cause serious complications and even death.

The conventional system of referring from one specialist to another for an opinion about a patient fails when the patient is seriously ill and urgent attention is required.

For many years, the only emergency response to serious illness, which operated at all times and in a systematic way, was the cardiac arrest team. The cardiac arrest team and cardiopulmonary resuscitation (CPR) is an icon of medicine (Hillman et al. 2001). Unfortunately, hospital CPR is futile in more than 90% of cases (Hershey and Fisher 1982; Tunstall-Pedoe et al. 1992). Despite the poor outcome, there has been little to prompt restraint (Priestley et al. 2004) and as a result, it is increasingly difficult to die in hospital without CPR being attempted (Hillman et al. 2001). It also seems ironical that so much research has been devoted to detailed aspects of CPR, such as the most effective doses of drugs and how many cardiac compressions, when it is often an inappropriate and futile perimortem ritual (Hillman et al. 2001).

Interestingly, a shock team was described in 1967 (Frank 1967) to identify seriously ill at-risk patients with shock and to provide a more rapid and appropriate response to the patient. This is a limited and small group of patients requiring a specialised response. Nevertheless, it was one of the first attempts to acknowledge the complications of delayed management of patients with life-threatening problems. A more successful model for the management of the seriously ill has occurred with severe trauma (Pagliarello et al. 1992; Shackford et al. 1986). Patients are identified by a combination of physiological, anatomical and disease criteria. They are rapidly triaged to the most appropriate hospital site, and then managed according to standardised protocols by staff with appropriate skills and experience (Shackford et al. 1986) The Medical Emergency Team (MET) concept is based on the same principles as the management of seriously ill at-risk trauma patients.

The Medical Emergency Team concept and MET-type systems

The concept of a MET was first established in Liverpool Hospital in Australia in 1989. The system was based on defining a seriously ill patient in terms of serious vital sign abnormalities and observational states – the so-called MET criteria (Hourihan et al. 1995; Lee et al. 1995). The vital sign abnormalities are extremes of pulse rate and respiratory rate, as well as hypotension. Added to these are the observational criteria: threatened airway, seizures and a sudden decrease in level of consciousness. An important final criteria is "serious concern", covering the situation where bedside staff are worried about the patient's state and where it does not necessarily fit in with other criteria and/or where staff feel unable to deal with the situation.

If any of these criteria are met, the old cardiac arrest system is activated and the MET called. Staff comprising the MET would need to be available at all times and would also need to have the skills, knowledge and experience to deal with all medical emergencies in a hospital. Results of the MET were first published in descriptive

The factors which make hospitalised patients vulnerable to deterioration include: disjointed islands of care; doctors not adequately trained in acute medicine and resuscitation; nurses who record and observe deteriorating patients, but are not engaged with an appropriate response system; and a population of patients who are often old with multiple co-morbidities.

studies (Hourihan et al. 1995; Lee et al. 1995). Other studies in different environments followed (Daly et al. 1998; Parr et al. 2001).

Out of the MET system came the theme of outreach teams in the United Kingdom (Bright et al. 2004; Counsell 2001; Cuthbertson and Webster 1999; Goldhill et al. 1999). Other early response systems using criteria similar to those of the MET system were developed (Bright et al. 2004; Cioffi 2000; Goldhill 1997; Goldhill et al. 1999). Some of the systems include the Patient-at-risk team (PART) (Goldhill et al. 1999), the early warning scoring system (EWSS) (Morgan et al. 1997), and the modified early warning score (MEWS) (Stenhouse et al. 2000).

In 1999, the UK Department of Health established a working group to examine the delivery of critical care services (2000). The resulting document, "Comprehensive Critical Care", recommended that a broader approach to caring for the seriously ill be undertaken, including critical care services outside the boundaries of ICUs and HDUs. The outreach concept takes many forms in different hospitals. These include hospital-wide education and awareness programmes as well as nurse and/or doctor led teams similar to the MET concept.

Studies evaluating MET and MET-type concepts

As yet, there are few studies evaluating the impact of MET-type systems and outreach programmes. One of the first was a study comparing a hospital with a MET system with 2 hospitals without a MET system over a 6 month period (Bristow et al. 2000). There was a significant reduction in unplanned admissions to the ICU in the MET hospital, and a reduction in non-NFR deaths in one of the control hospitals. After adjustment for variables, there was no significant difference in potentially reversible cardiac arrest rates.

A before/after study in one hospital showed a significant reduction in cardiac arrest rates as well as mortality as a result of cardiac arrest rates (Buist et al. 2002). Another before/after study after implementation of a MET system also showed a significant reduction in potentially preventable cardiac arrest rates, as well as overall death rates and a highly significant reduction in ICU bed days as a result of a cardiac arrest (Bellomo et al. 2003). The same group demonstrated a reduction in postoperative adverse outcomes (Bellomo et al. 2004). Only one evaluation of the outreach programme to date has demonstrated a reduction in mortality in general hospital wards (Priestley et al. 2004).

Where to next?

It is unlikely that anyone practising acute medicine would advocate that we wait until a patient dies or has serious complications before they are managed by staff with appropriate skills, knowledge and experience. We need to explore better ways of identifying potentially at-risk patients at an earlier stage in their illness and of developing a system which will respond early and manage care appropriately. This challenge will require a system perspective rather than relying on the traditional *doctor:patient* relationship.

This process needs to be constructed around patient needs rather than within traditional silos. There are an increasing number of seriously ill at-risk patients in hospitals. This contributes to large numbers of potentially preventable deaths and serious complications, often preceded by well documented antecedents for many hours before their event. We need to understand more about this patient population in order to develop a standard way of defining the incidence. We need to understand more about the incidence and nature of adverse events in hospital patients and finally to evaluate the impact of various interventions.

Intensivists will be intimately involved in the delivery of MET-type concepts. Further research around this population of patients is required to secure the best outcome for at-risk patients in our hospitals.

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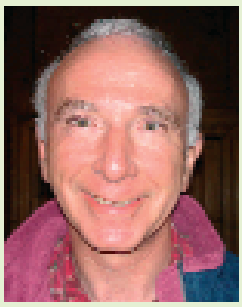
Identifying **high risk patients** on the **ward**

Hospital wards may contain patients who are, or may become, critically ill. They can usually be identified by abnormal physiological values. Early intervention may be beneficial.

Table 1: Medical Emergency Team call-out criteria (Buist et al. 2002)

Airway	respiratory distress, threatened airway
Breathing	respiratory rate < 6 or > 30, SpO_2 < 90% on oxygen, difficulty speaking
Circulation	systolic blood pressure < 90 despite treatment, heart rate > 130
Neurology	unexplained decrease in consciousness, agitation or delirium, repeated or prolonged seizures
Other	concern about patient, uncontrolled pain, failure to respond to treatment, unable to obtain prompt help

Note: Other METs may have different criteria



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The intensive care unit (ICU) is only one place in which critically ill patients receive care. Events before and after ICU admission are relevant to the outcome of these patients. In a group of British hospitals, patients admitted to ICU from hospital wards had a 53% mortality (Goldhill and Sumner 1998) and the longer patients were in hospital before ICU admission the higher their mortality (Goldhill *et al.* 2004). Patients who died after being admitted to ICU from the wards were in hospital a median of 3 days before ICU admission. Some 22% of admissions from the ward received cardiopulmonary resuscitation before ICU. These patients had a 79% mortality and constituted 33% of the deaths of ICU admissions from the wards (Goldhill *et al.* 2004). Furthermore 27% of deaths took place after the patients had survived their first ICU admission to be discharged back to the wards (Goldhill and Sumner 1998). This particularly applied to relatively 'low risk' patients, those with a predicted mortality by APACHE II (Knaus *et al.* 1985) of less than 20%. Patients on the wards are accessible and there is often time to intervene. If intensive care outcome is to improve, events on hospital wards, before and after ICU admission, must be addressed.

Typically only 2% to 4% of hospital beds are in ICUs or High Dependency Units (HDU). The total number of acute hospital beds has fallen over the last 20 years (Capewell 1996; Hensher and Edwards 1999). Ward patients tend to be sicker (Sparkes *et al.* 2004), doctors may have poor knowledge of critical illness (Cook and Smith 2004; Smith and Poplett 2002), there aren't enough trained nurses (Finlayson *et al.* 2002) and shorter working weeks disrupt continuity of care. Experience suggests that critically ill patients on wards may be unrecognised or unable to gain admission to a critical care unit at the appropriate moment.

Intensive care scoring systems predicting hospital mortality, such as APACHE II (Knaus *et al.* 1985), are based primarily upon deranged physiological values. Several studies demonstrate that abnormal physiological values are commonly recorded in the charts of ward patients in the hours preceding cardiorespiratory arrest, unanticipated ICU admission or death (Buist *et al.* 1999; Chaplik and Neafsey 1998; Franklin and Mathew 1994; Goldhill *et al.* 1999[1&2]; Hillman *et al.* 2001; Hodgetts *et al.* 2002; Kause *et al.* 2004; Rich 1999; Sax and Charlson 1987; Schein *et al.* 1990; Smith and Wood 1998).

In Australia medical emergency teams (METs) (Lee *et al.* 1995) have been shown to decrease the numbers of cardiac arrests and hospital deaths (Bellomo *et al.* 2003; Bellomo *et al.* 2004; Buist *et al.* 2002) MET call-out criteria are based upon markedly deranged physiological values as well as concern by ward staff (table 1).

The use of physiological values in the form of an early warning score (EWS) to identify at-risk ward patients was first described by Morgan (Morgan *et al.* 1997). There are many different formats but they follow a similar theme, awarding points for varying degrees of derangement of different physiological systems (Goldhill 2001). The higher the total score the more 'at risk' the patient. The EWS used at the Royal London Hospital (PAR score) is shown in table 2.

To date EWSs have been devised using clinical acumen and common sense. They have yet to be scientifically

Table 2: The Patient-At-Risk early warning score

	Points Scored						
	3	**2**	**1**	**0**	**1**	**2**	**3**
Temperature; °C	-	<35.0	35.0-35.9	36.0-37.4	37.5-38.4	≥38.5	-
Heart rate; beats/minute^{-1}	<40	-	40-49	50-99	100-114	115-129	≥130
Systolic blood pressure; mmHg	<70	70-79	80-99	100-179	-	≥180	-
Respiratory rate; breaths/minute^{-1}	-	<10	-	10-19	20-29	30-39	≥40
SpO_2; %	<85%	85-89%	90-94%	≥95%	-	-	-
Level of consciousness	-	-	-	alert	confused	responds to voice	responds to pain or unresponsive
Urine output; Ml/kg^{-1}/hour^{-1}	nil	<0.5	dialysis*	0.5-3	>3	-	-

**dialysis: normally dialysis dependent*

validated as predictors of preventable adverse outcomes. The score generated depends crucially on the definition of normal physiological values and how much importance the score's creators have attached to the derangements of each of the physiological parameters measured.

Using the definition of normality from the PAR score a point prevalence study was undertaken of all in-patients outside the ICU on a single day at a University hospital in London. Some 11% had three or more physiological abnormalities and a 30-day hospital mortality of 21.3% (Goldhill and McNarry 2004). A further 20% had two abnormalities and their 30-day mortality was 9.2%. There was only one death within 30 days among patients with no recorded abnormalities, and this death occurred 21 days after the measurement day. The same study reported that patients cared for in a ward area that was judged inadequate for their needs had an increased mortality.

Data from 1047 patients seen by an intensive care outreach service showed that the number of physiological abnormalities was associated with hospital mortality, and an increasing PAR score was associated with decisions to admit to a critical care area, limit treatment and also with hospital mortality (Goldhill 2005). Multiple logistic regression analysis looking at the contribution of the seven physiological variables showed that all, except temperature, contributed to the decision to admit to critical care or limit treatment, and all, except temperature and heart rate, contributed to a prediction of hospital mortality. Graphing physiological values against hospital mortality suggested that extremes of all seven variables were associated with increased hospital mortality.

There is evidence to suggest that early intervention may improve the outcome of critically ill patients (Ball *et al.* 2003; Bennett 2002; Goldhill *et al.* 19993; Priestley *et al.* 2004; Rivers *et al.* 2001; Story *et al.* 2004). The implementation of a system to ensure regular, accurate measurement and recording of physiological values at the bedside should be possible. We would suggest that this is an essential part of any hospital-wide system to identify and manage high-risk ward patients.

Conclusion

Patients who are, or may become critically ill, are to be found on hospital wards. They have a high mortality and commonly deteriorate to the point of cardio-respiratory arrest before ICU admission. Early intervention may be beneficial and there is opportunity to intervene as these patients are often in hospital for days or weeks before ICU admission or death. Many of these patients can be recognised by their abnormal physiological values. An early warning system based upon physiological measurement has the potential to identify and track these patients.

References are available on request: editorial@icu-management.org

Managing **implementation** of Medical Emergency Teams in **Australia**

Nancy Santiano and colleagues explain the objectives of Medical Emergency Teams and experiences towards successful implementation and management of this new concept throughout a health service area in Australia.

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Introduction

Critical Care Outreach Teams (CCOT) have the following objectives: to prevent ICU admissions and/or ensure that admissions to ICU are timely, to support recovery of patients post discharge from ICU, to share critical care skills with staff on the general wards, and enhance training and skills thereby improving critical care services (UK Department of Health 2000). This article describes the Medical Emergency Team (MET) system, our experiences in developing the initiative and how the MET meets the objectives of the CCOT.

The MET System

The MET was designed to identify seriously ill patients and provide a rapid response before the patient suffers a serious complication, such as a cardiorespiratory arrest or death (Hillman et al. 2001). The MET system provides emergency medical care 24 hours a day in all hospitals of the South Western Sydney Area Health Service (SWSAHS), which serves a population of over 700,000 people (Australian Bureau of Statistics 2000).

The criteria

A clear and simple set of calling criteria are used by staff to identify physiological changes in a patient's condition (Hourihan et al. 1995). Clinical and non-clinical staff members are able to activate the MET, and may call if they are seriously worried about a patient, or if one of the physiological criteria is observed. The MET calling criteria are displayed prominently throughout the hospital, and are also attached to staff badges (table 1).

MET response

The MET responds from either the Intensive Care Unit (ICU) or the Emergency Department (ED). The number and composition of the team vary depending on the size and needs of the hospital, but usually includes at least a doctor and a nurse (see table 2). MET members perform their normal duties in addition to responding to medical emergencies. The MET is fully equipped with an emergency pack with drugs and equipment (see figure 1). The MET manages and stabilises the patient during the period of acute deterioration and then formulates a plan of care with the admitting team (Cretikos and Hillman 2003).

Table 1: The Medical Emergency Team calling criteria (Hourihan et al. 1995)

Airway	Threatened
Breathing	All respiratory arrests
	Respiratory Rate <5 and >36
Circulation	All cardiac arrests. Pulse Rate <40 and >140
	Systolic Blood Pressure <90
Neurology	Sudden fall in level of consciousness (fall in GCS of >2 points)
	Repeated or prolonged seizures
Other	Any patient you are seriously worried about that does not fit the above criteria

Education

TEAM

It is imperative that at least one of the members of the MET is trained in advanced resuscitation. The Advanced Resuscitation Course (ARC) ensures that there are appropriately trained personnel within the area health service 24 hours a day (SWSAHS 2003). The ARC is a 6-month self-directed course with criterion-based assessments.

CLINICAL AND NON CLINICAL STAFF

Staff are educated on how and when to call the MET. The MET system is one of the key sessions in all hospital orientation and annual mandatory training programs. Ward staff are encouraged to participate during the medical emergency to facilitate acquisition of knowledge and skills. Educational sessions are conducted on early warning signs and other physiological parameters, as well as specific cases identified by the MET coordinator during the surveillance process.

Evaluation and monitoring system

A fundamental component of any health system is the collection of data. Clinical outcome indicators were developed to monitor and evaluate the MET system. Data is collected on MET utilisation, unexpected deaths, cardiorespiratory arrests and unplanned ICU admissions. Patients with "Do not resuscitate" orders are excluded (Cretikos and Hillman 2003; Hillman et al. 2000; Hillman et al. 2001; SWSAHS 1999).

Challenges

Although the MET system was developed at Liverpool Hospital in 1990, overall implementation throughout

SWSAHS was only partially successful. Prior to 2004, maintenance of the MET system was problematic. Due largely to insufficient resources, MET system roles were only carried out if other duties allowed sufficient time. Our experience suggests that effective implementation of the MET system requires consistent monitoring, follow up, feedback, reinforcement and nurturing in order to facilitate cultural change. The system should become part of the hospital's patient safety and quality framework.

The MET coordinator role for patient safety

Following enquiries into allegations of suboptimal care leading to adverse events at two hospitals, the SWSAHS decided to focus attention on mechanisms to ensure patient safety. Funds were allocated to provide appropriate support and resources for the MET system. A MET Coordinator (senior critical care registered nurse) was appointed in each of the hospitals to coordinate and implement a strategic plan, on a full- or part-time basis depending upon the size of the hospital.

The MET coordinator role became the lynch pin in the hospital's patient safety and quality system. The MET coordinator provides surveillance of the MET outcome indicators including a daily death screening and review process. The MET data is collected and reported to everyone who has a stake in patient safety. These individuals take ownership of the data and are able to implement and facilitate improvements in practice.

Perceived barriers to MET utilisation

Nurses play a critical role in the MET system, as they initiate up to 90% of the MET calls. For this reason, nurses were the focus of an evaluation after the MET re-implementation process. Questionnaires and focus groups were used to explore perceived barriers and factors that may have improved effective MET utilisation.

The following barriers were identified:

Nurses may experience anxiety when calling due to uncertainty about the patient's severity of illness; Nurses have difficulty in interpreting unclear withdrawal of treatment orders such as "Not for resuscitation, but still for MET"; Nurses in specialised units (maternity, paediatric and operating theatres) were less likely to call the MET, because they believed that they should be able to manage specialty-specific emergencies themselves; The MET system may place further strain on under resourced ICUs or EDs; Negative attitudes from the MET members directed at ward staff during the call; Lack of experienced MET members skilled in resuscitation; Insufficient follow through of education about the MET system and its effectiveness; Shortages of staff and insufficient equipment possibly delaying monitoring of vital signs; Inadequate ongoing management of patients who were left on the ward after the MET call; A low prevalence of medical staff had received MET education.

Results demonstrated that calling a MET is complex and may require a collaborative and collective approach to decision making (Cioffi 2000).

Table 2: MET composition at SWSAHS

Tertiary and urban hospital	ICU registrar or resident (team leader), designated ICU registered nurse, medical or surgical registrar
Small rural hospitals	Designated ICU or ED nurse with advanced resuscitation training, ward nurse

Benefits of the MET system

The MET has been shown to significantly reduce the incidence of mortality from unexpected cardiac arrest in hospital (Bellomo et al. 2003; Buist et al. 2002), surgical length of stay (Bellomo et al. 2004), cardiac arrest and overall in-hospital mortality (Bellomo et al. 2003).

In addition, the MET has less tangible benefits to staff and the organisation. The nurses viewed the MET system as an effective way to initiate intervention for patients they were concerned about. The MET system provides room for staff to display initiative and become pro-active when confronted by seriously ill patients. Nurses believe it is "their system" to use. It also provides a sense of support and security for the junior medical and nursing staff (Cretikos and Hillman 2003). The MET system incorporates a basis for clinical governance by providing information and feedback, and provides a framework for the continuous monitoring of hospital quality and patient safety (Hillman et al. 2000). The employment of the MET coordinators throughout SWSAHS improved MET utilisation, data collection, surveillance and monitoring of outcome indicators, communication and camaraderie between hospitals.

Conclusion

The MET System meets the objectives of CCOT, providing early interventions for patients at risk of clinical deterioration and ensuring optimal management of the patient during the emergency. The employment of a MET coordinator in all hospitals has improved education of staff, data collection, monitoring and feedback. Timely reporting has provided an avenue for regular dialogue between critical care units and general ward areas. Implementing a MET should be viewed as a complex system intervention, which requires attention to education and awareness, culture change and continuous monitoring and support from a dedicated MET co-ordinator.

Figure 1: The SWSAHS MET pack (1999)

References are available on request: editorial@icu-management.org

A law for end of life care in France

After a case of euthanasia attracted attention in France in 2003, the Parliament adopted a legislation last November, which allows withdrawal of life support in terminally ill patients. The new law will guarantee judicial security to physicians who comply with its provisions.

Introduction

In November 2004, the lower Chamber of the French Parliament voted unanimously for a law on the "Rights of patients and end of life" (http://www.assemblee-nat.fr/12/dossiers/accompagnement_fin_vie.asp). Although the law still requires approval by the Senate, the Higher Court, it is highly likely that this law will not be altered and that its main provisions will remain. This will be a major step forward for French critical care physicians, as it clearly allows the withdrawal of life support in desperate situations, when prolongation of intensive care is deemed "futile", or as it is described in France, only due to physicians' "unreasonable obstinacy". In spite of the fact that nearly all scientific societies concerned with end of life care have issued consensus documents and recommendations (American Medical Association 1991; British Medical Association 1999; Ferrand 2002; Lanken 1991; Orsi 2002; SCCM 1998; Swiss Academy of Medical Sciences 1995), national legislations are usually relatively unclear. The laws on "active" euthanasia issued in the Netherlands and more recently in Belgium proved to be of little help in ICUs. Recent rulings in several countries have also shown that Justice, by and large, is not at ease with withdrawal of life support (Damas et al. 2001; Maggiore and Antonelli 2005; Rocker 2003), increasing the physicians' feeling of judicial insecurity.

In September 2003, the Vincent Humbert criminal case generated the momentum needed to push France into undertaking a major legislative advancement. It was reported that Vincent Humbert, a twenty year-old fireman, had died after his physician, Frederic Chaussoy, withdrew mechanical ventilation (Blanchard 2003). Three years earlier, following a car accident, Vincent had been left quadriplegic, blind and mute, but he had recovered full consciousness and could communicate with his mother through movements of his thumb. When he realized that his condition would never improve, he asked for his life to be terminated, which his physician refused. Ultimately, only his mother accepted his request; she administered a fatal dose of Nesdonal® through his gastric tube. However, when it was disclosed that Vincent was dying, he was intubated and rushed to an ICU. After 36 hours of mechanical ventilation, the intensive care physician in charge, Dr Frederic Chaussoy, under huge pressure from Vincent's family and the media, decided to withdraw life support, injected Nesdonal® and, as it was learnt later, intra venous potassium chloride. Marie Humbert, Vincent's mother, was charged with "attempted murder", and Frederic Chaussoy was charged with "poisoning", the penalty for which could be a life sentence. The case raised considerable emotion all over the country, with both of the accused being overwhelmingly supported by people and physicians. Ministers disclosed publicly their division over the case and in October 2002, Parliament nominated a Commission which would advise the Government on whether or not to rule on euthanasia and end of life medical decisions. The Commission, led by Jean Leonetti, gave its conclusion in July 2004 and proposed a law on "Rights of patients and end of life". After an exceptionally short time, the law was approved by the lower Chamber in November.

The new law states that physicians can withhold or withdraw any treatment deemed "useless or disproportionate", thus ending physicians' "unreasonable obstinacy", when it has only the prospect of the perpetuation of agony. It is interesting to note here that North American documents, consensus statements (Lanken 1991) and rulings describe useless care which can be withdrawn as "futile" (Helft et al. 2000; AMA 1999), a relatively objective concept. Conversely, Europeans, or at least those from the Southern part of Europe (France included), refer to it as "unreasonable obstinacy", a psychological or moral attitude.

Another essential provision states that alleviation of pain or suffering can be achieved via escalating doses of sedatives/analgesics (opioïds), even if it can shorten the patient's life. The explicit intent of the law maker is to encourage and promote the use of opioïds at the end of life, by curbing the physicians' fears that they could be sued for homicide when doing so. This is recognition of the "double effect", a concept stemming from catholic theology, adapted specifically for end of life decisions in ICUs by the Pope Pie XII in 1957, and since recognized by the US Supreme Court (Quill et al. 1997).

Another innovation is the statement that any treatment, when futile, can be withdrawn. Any treatment, as explained by the law makers themselves, includes artificial nutrition, which, accordingly, can also be withdrawn. This will potentially help when clinicians and

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families are facing agonizing decisions concerning patients with permanent vegetative states (PVS). Common law in the US (Luce and Alpers 2001) and the UK (Wade 2001) has for a long time accepted that stopping nutrition and fluids is permissible if requested jointly by the caring team and the family. However, the recent Schiavo case in Florida has revealed that even in the US the acceptance of the removal of a gastric tube in a case of PVS may be debated (Silverman 2005). A recent study performed in the US state of Oregon, where medical assisted suicide is legally accepted, has demonstrated that deaths were peaceful when patients at the end of their lives chose voluntarily to stop drinking and eating (Ganzini et al. 2003).

Physicians' respect of a patient's refusal of care, even if death could ensue, has been reiterated in the new law. Although already written in an earlier French law ("Rights of patients", March 2002), this was never applicable, because it was too vague. During the summer of 2002, based on the "Rights of the patients" law just passed, a Jehovah witness who was transfused – and saved – against her will sued the physician who ordered the blood transfusion. However the charge was dismissed by the Higher Court, on the basis that he had saved his patient's life, which had a higher value than respecting her will and autonomy (Lemaire 2003). In order to prevent such a situation from happening again, the new law now states that when life is at stake, refusal of care has to be repeated after a "reasonable delay" before it is accepted. This guarantees that such decisions cannot be taken in an emergency. Of course, tradition, culture and law are markedly different in Southern Europe and in the more northern countries and the US, where the respect of autonomy justifies that a physician is legally allowed not to oppose his or her patient's death (Knuti et al. 2003).

A major breakthrough is that the new law will authorize the limitation and withdrawal of life support in patients unable to consent by themselves. We have seen that laws worldwide may be clear on the obligation for physicians to respect any refusal of care expressed directly by the patient him- or herself, but they are usually far more imprecise when he or she is unconscious. The new

North American documents… describe useless care, which can be withdrawn as "futile", a relatively objective concept: Europeans… refer to it as "unreasonable obstinacy", a psychological or moral attitude.

French law states that "…at the end stage of hopeless diseases, the physician is allowed to withhold or withdraw useless or disproportionate treatment…" Of course there are stringent conditions, which are: first, the decision has to be taken on a collegial basis; second: the family needs to be informed, and the advice of family members taken into consideration; and third, the decision must be written in the patient's medical files. Note that family members have no decision-making capacity here. This is a common European attitude, shared by the British Medical Association (1999), which states: "In England…no other individual has the power to give or withhold consent for the treatment of an adult who lacks decision-making capacity… Those close to the patient can provide important information whether the patient would have considered life support treatment to be beneficial. Whilst the views of those close to the patient are an important factor to take into account in reaching treatment decisions… ultimately, the treatment decision is not their right or their responsibility. Rather, the decision will be made by the clinician in charge of the patient's care on the basis of what he or she considers will benefit the patient." This is clearly at odds with the North American standard, which gives preeminence to family members, with the physician only advising. In the US, the decision making capacity is given to the family as an extension of patient's autonomy (Lanken 1991; SCCM 1988; Wade 2001).

The law will take effect when it is enacted by the Higher Chamber; physicians will then no longer fear accusation of murder when withdrawing useless treatments, as long as they act in compliance with the new rules. The law will certainly clarify the debate on euthanasia, which will be focused on what it is: giving death to a person at his or her request, which has nothing to do with ending useless care to critically ill patients, but is rather the difference between terminating life or letting someone die.

References are available on request: editorial@icu-management.org

Monitoring blood gasses and metabolic parameters at the bedside: clinically and economically justified?

Preventing hyperglycaemia and electrolyte disorders and optimizing ventilator settings can help prevent complications, thereby decreasing morbidity and length of stay in the ICU. On-site analysis may help in maintaining metabolic homeostasis, thereby improving outcome and reducing costs.

Introduction

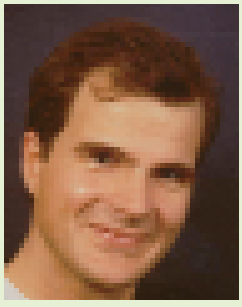
On-site blood gas analyzers can be used to monitor blood gasses and guide ventilator settings, and also to quickly assess parameters such as hematocrit and serum levels of glucose and various electrolytes. This article focuses on clinical aspects of bedside blood gas analysis, and also touches on cost implications.

Electrolyte disorders

Electrolyte disorders can be found with high frequency in critically ill patients. Clinical problems may arise both when electrolyte levels are excessively high or low. The most frequent cause of high electrolyte levels, especially hyperkalemia and hyperphosphataemia, is renal failure with oliguria or anuria. However, electrolyte depletion is a far more common finding in critically ill patients. For example, Wong and associates found hypomagnesaemia in 65% of patients admitted to an intensive care unit, compared to 12% of patients in a general ward (Wong et al. 1983). We observed significant electrolyte disorders in 20%-90% of our patients at ICU admission, depending on the category of patients (Polderman et al. 2000[1,2] Polderman and Girbes 2004). Apart from manifest renal dysfunction, electrolyte disorders were found most frequently in patients with various types of neurological injury (Polderman et al. 2000[1,2]) and those admitted following cardiac surgery with use of extra-corporeal circulation (Polderman and Girbes 2004).

Electrolyte disorders in critically ill patients are often caused by subtle renal disorders such as tubular dysfunction, often occurring in patients admitted to the ICU. Tubular dysfunction often leads to excessive electrolyte loss. This problem can be significantly exacerbated by treatments commonly used in the ICU, such as administration of diuretics (including osmotic diuretics such as mannitol), vasoactive drugs such as norepinephrine and dopamine, antibiotics such as aminoglycosides and pipracillin, and many others (Polderman et al. 2002; Brown and Greenwood 1994; Smit et al. 1995; Weisinger and Bellorin-Font 1998). In addition, diverse interventions such as nasogastric suction, fluid administration and induction of hypothermia can further increase electrolyte loss (Polderman at al. 2001; Weisinger and Bellorin-Font 1998). Finally, initiation of continuous veno-venous haemodialysis for acute renal failure can also lead to severe electrolyte disorders.

There is convincing evidence that electrolyte disorders can have severe consequences in critically ill patients. The link between sodium disorders (both hypo- and hypernatraemia) and adverse outcome is well recognized (Kumar and Berl 1998) and has led to its inclusion in various severity of illness (risk adjustment) scores such as the APACHE-II score (Knaus et al. 1985). It is also well known that hypokalaemia can cause complications such as muscle weakness, rhabdomyolysis, renal failure and hyperglycaemia as well as cardiac arrhythmias, especially in patients with ischemic heart disease. For this reason levels of sodium and potassium are usually monitored carefully in severely ill patients. However, disorders of other electrolytes may have similarly negative consequences, although these are often monitored far less frequently. For example, hypomagnesaemia has been linked to adverse outcome and increased mortality both in the intensive care (Chernow et al. 1989; Rubeiz et al. 1993) and general ward (Chernow et al. 1989). Although this does not necessarily imply a causal relationship (hypomagnesaemia could simply be a marker of more severe illness) there are various plausible mechanisms through which outcome could be directly influenced. Clinical studies have shown that hypomagnesaemia is linked to the occurrence of severe arrhythmias and adverse outcome in patients with unstable angina or myocardial infarction (Abraham et al. 1986; Kafka et al. 1987) and that administering magnesium can reduce mortality and infarction size in this category of patients (Teo et al. 1991; Woods et al. 1992). Hypomagnesaemia can also lead to insulin resistance and hyperglycaemia (Polderman et al. 2003; Weisinger and Bellorin-Font 1998) which in turn may adversely affect outcome; effective control of blood sugars has been shown to reduce mortality and length of stay at least in post-surgical patients (Van den Berghe et al. 2001). Another issue is the possible role of magnesium in neurological injuries; a range of animal studies has linked hypomagnesaemia to the development of additional and more severe neurological injuries, while administration of magnesium before or after the injury prevents or mitigates these injuries (Polderman et al. 2003; Vink and Cernak 2000). This issue has not yet been properly addressed in clinical studies.



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Other electrolyte disorders may also adversely affect the clinical course of critically ill patients. Hypophosphataemia can induce muscle weakness including weakness of the diaphragm and respiratory muscles, leading to an increased rate of respiratory infections and failure to wean (Aubier et al. 1985; Fisher et al. 1983; Gravelyn et al. 1988; Varsano et al. 1983). In addition, hypophosphataemia can decrease myocardial output and may induce arrhythmias, especially in patients with pre-existing myocardial ischemia (O'Çonnor et al. 1977; Ognibene et al. 1994). Hypocalcaemia can also lead to arrhythmias, as well as to muscle weakness with severe cardiovascular depression and congestive heart failure, gastro-intestinal disorders and renal failure (Bushinsky and Monk 1998; Connor et al. 1982; Drop 1985; Zaloga and Chernow 1986).

No studies specifically dealing with the financial consequences of electrolyte disorders have been performed. However, as electrolyte disorders have been linked to specific complications such as arrhythmias, increased infection rates and failure to wean, it seems highly likely that length of stay will be increased by electrolyte disorders. Although it has not been shown that correcting these disorders improves outcome and reduces length of stay this appears to be a reasonable assumption; moreover, such improvements have been reported in specific categories of patients such as those with myocardial infarction (Rasmussen et al. 1986; Shechter et al. 1990; Teo et al. 1991; Woods et al. 1992). Maintaining electrolyte levels within a narrow range is thus an important goal of therapy in the ICU, especially in neurocritical patients in whom the (injured) brain is more susceptible to the potential consequences of electrolyte disorders, including hypotension, cerebral vasospasms, cardiac arrhythmias and hyperglycaemia (Polderman et al. 2003).

Because electrolyte disorders often have the same causes there is a high likelihood that different disorders will occur simultaneously, especially in critically ill patients. This significantly increases the risk for clinical manifestations. Moreover, the risk of complications like arrhythmias increases in patients with pre-existing myocardial disease. An additional problem is that electrolyte disorders can develop very swiftly; we observed a 50% decrease in serum electrolyte levels 6 hours after induction of hypothermia in patients with severe traumatic head injury (Polderman et al. 2001).

All this implies that frequent measurements and supplementation of different electrolytes may be required to maintain electrolyte levels in the normal range in particular categories of patients at specific times.

Glucose levels

Tight regulation of blood glucose levels has become an important goal of therapy in critically ill patients, as intensive insulin therapy to prevent hyperglycaemia has been shown to reduce mortality and improve outcome in various categories of ICU patients (Finney et al. 2003; Van den Berghe et al. 2001). This has led to a much more aggressive treatment of hyperglycaemia in many ICUs worldwide, implying that much more frequent assessments of blood sugar levels will be needed. Some studies have reported improved glycaemic control through use of strict protocols and standardization of intensive insulin therapy (Finney et al. 2003). On site measurements may help implement such protocols.

Blood gasses

Blood gasses are used to guide ventilator settings in mechanically ventilated patients. In most patients peripheral saturation measurements can be used as an additional tool to assess oxygen levels and prevent hypoxia. On-site blood gas analysis will provide additional benefits in patients in whom peripheral saturation is difficult to measure and/or in whom this measurement does not correlate well with actual oxygenation. In addition, prevention of hypocapnia may be an important goal of therapy, especially in patients with neurological injuries; severe hypocapnia (usually defined by CO_2 levels below 30 mmHg) can lead to constriction of cerebral arteries and local ischemia, especially of injured areas. Note also that blood gas measurements are temperature dependent; levels of oxygen decrease by ±4mmHg/^{O}C, and carbon dioxide levels by ±2mmHg/^{O}C when temperature decreases. These differences are particularly important when, for example, mixed venous saturation is measured; a small difference in measured pO2 due to temperature or if the patient has high fever or a very low temperature, will significantly effect the measurement. It is easier to correct for these temperature effects properly when measurements are performed on site.

Conclusion

Critically ill patients have a very high risk of quickly developing electrolyte disorders and hyperglycaemia. These disorders can lead to complications which adversely affect outcome and increase length of stay. The evidence suggests that these adverse consequences can be prevented or mitigated by preventing or promptly correcting these disorders. It therefore makes sense to measure electrolyte levels and glucose levels on site in the ICU, to allow more frequent measurements, decrease errors due to incorrect temperature input, and allow quicker therapeutic interventions, guided by these measurements in high-risk patients.

References are available on request: editorial@icu-management.org

Clinical pharmacological studies in the **neonatal** ICU with intravenous **paracetamol**

The relevance, feasibility and methodology of pharmacokinetic studies in neonates during intensive care are illustrated by some recently published studies on intravenous paracetamol.

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Introduction

Many drugs in neonates and children are still prescribed off-label or are unlicensed. Although this problem is already of relevance in the out-hospital setting (30%), it is most prominent in paediatric (70%) and neonatal (90%) intensive care settings (Turner et al. 2003). It is therefore obligatory that population-specific data on drug-specific pharmacokinetics and -dynamics are collected to secure quality, safety and evidence based prescription of drugs in the near future. The high off-label prescription rate in intensive care patients further emphasizes the necessity for clinical research in the intensive care setting.

Studying neonatal populations: measures and methodologies

Although general principles of clinical pharmacology also apply in neonates, the characteristics of this population warrant a specific approach. Body water content, fat disposition and muscle mass are markedly different, all hepatic clearance processes have a distinct iso-enzyme specific ontogeny and renal clearance in early neonatal life is low (Kearns et al. 2003; Van den Anker 1996). Besides biological changes, there are also population-specific methodological issues which need consideration, such as scaling and sampling.

Relevant co-variables of pharmacokinetics in neonates are postnatal, postconception age and weight (Kearns et al. 2003; Van den Anker 1996). Weight is often the first co-variable evaluated in paediatric populations, but it is important to appreciate the limitations of the scaling for size (Anderson and Meakin 2002; Anderson et al. 2000). While body weight is most commonly used, a non-linear relationship is recognized between weight and dose. Body surface area is also used, but the allometric 3/4 power model may be a more appropriate scaling, based on the observation that the logarithmic of basal metabolic rate with weight produces a straight line with a slope of 3/4.

In this article, we illustrate the feasibility and relevance of pharmacokinetic studies during childhood through recently published studies on intravenous paracetamol disposition.

Pharmacokinetics and metabolism of intravenous paracetamol in neonates

Paracetamol is a readily available analgesic and antipyretic. It is the most often prescribed drug for treatment of mild to moderate pain in infants, including neonates (Allegaert et al. 2004). In adults, paracetamol is almost exclusively eliminated by the kidney after conjugation to either glucuronic acid (paracetamol-glucuronide, 50-60%) or sulphate (paracetamol sulphate, 25-35%). A maturational trend with a progressive increase in paracetamol-glucuronide elimination has been described in several single dose paracetamol studies, reaching an adult pattern at the age of 8-10 years (Allegaert et al. in press; Anderson et al. 2002; Miller et al. 1976).

Due to lack of data, we first performed a single dose study in neonates (day 1) (Allegaert et al. 2004). We were hereby able to document the gestational age-based maturation of paracetamol terminal elimination half life (see figure 1).

Based on these findings, a repeated dose scheme was developed and studied. All concentration-time profiles were entered in a population pharmacokinetic analysis using a non-linear mixed effects model (NONMEM) to describe maturational aspects of pharmacokinetics of intravenous paracetamol in term and preterm neonates. Clearance increased from 2.85 L/70kg, CV 40.7% at 27 weeks PCA, to reach 7.05 L/h/70kg by 42 weeks PCA (standardised to a 70 kg person using allometric "1/4 power" models). These observations directed age-specific repeated dose regimes. A mean paracetamol steady state target concentration above 10 mg/L at trough can be achieved by loading dose of 40 mg/kg and maintenance doses:

– 20 mg/kg 6 h at 28-weeks,
– 25 mg/kg 6 h at 32 weeks,
– 30 mg/kg 6 h at 36 weeks, and
– 20 mg/kg 4 h at 40 weeks PCA.

Warning: propacetamol doses, for intravenous paracetamol 50% of dose (Allegaert et al. 2004).

Finally, to study metabolism, urinary samples were collected in neonates who were administered repeated intravenous propacetamol. A significant increase in the relative contribution of APAP-G to overall urinary paracetamol elimination (i.e. G/T ratio) with increasing

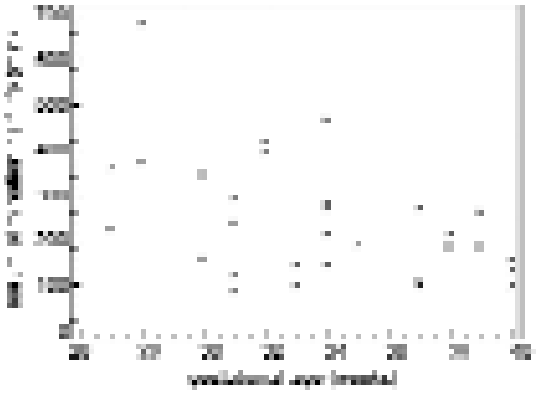


Figure 1: Elimination half life of intravenous paracetamol in neonates in the first day of life (adapted from Allegaert et al. 2004)

postnatal ($p<0.0001$) (see figure 2) and postconception age ($p=0.0055$) was observed while an increase ($p=0.0005$) in G/T ratio was documented during repeated administration and remained a significant variable to explain G/T ratio ($p<0.01$) in a multiple regression model (Allegaert et al. in press).

Discussion

We have used studies on paracetamol pharmacokinetics as a model to illustrate the feasibility and relevance of such studies in the intensive care setting.

A population pharmacokinetic approach enabled us to study the pharmacokinetic variability based on a limited number of samples/individual. With conventional approaches, a model is defined for each individual, based on the concentration/time profiles available. Pharmacokinetic variables are estimated based on these concentration/time profiles and can further be described and compared using a statistical approach. There are important prerequisites to using such a conventional approach (Anderson and Meakin 2002; Anderson et al. 2000). The number of observations in every individual should be adequate enough and a stringent interindividual sampling strategy is required to further reduce variability. In addition, within subject variability should be limited since estimated pharmacokinetic parameters are used as measured variables, resulting in limited accuracy to explore variability. Unfortunately, interindividual variability in pharmacokinetics is the most relevant question in neonates, while a frequent sampling strategy is more difficult to implement because of ethical considerations.

In a population approach, the entire population is modelled, which therefore eliminates the need to acquire sufficient data from every individual to define a predictive model. Population pharmacokinetics hereby provides a tool to learn more about what we need to know, providing data on degree and source of variation in the determinants of drug concentration-time profiles. In a non-linear mixed effects modelling (NONMEM) approach, all data from all individuals are fitted together with individual data on potential relevant biological variables, using a non linear regression analysis approach. Assumptions must be made regarding the form of variation in each parameter between individuals and regarding the distribution of the measurement error. Individual parameter values for some of the structural parameters are assumed to vary around the mean population value by a normal distribution. Variation between and within individuals is explained using statistical parameters within the modelling process (Anderson and Meakin 2002).

In conclusion, clinical trials of various medicines in neonates are required to provide evidence for safe and effective drug prescription in the near future. This will become an increasingly important issue in intensive care, with the very high prescription rate of off-label drugs. All contributors to paediatric drug development – regulatory authorities, ethics committees, physicians, the patient and his/her family and industry – need to play a role towards developing adequate and safe pharmacotherapy. In line with earlier initiatives, the activities within the European Medicines Evaluation Agency (EMEA) and the Paediatric Draft regulation reflect the increased awareness and scrutiny of 'the public'. Here we have illustrated the necessity, feasibility and methodology of such studies in neonates and young children, using intravenous paracetamol as a model.

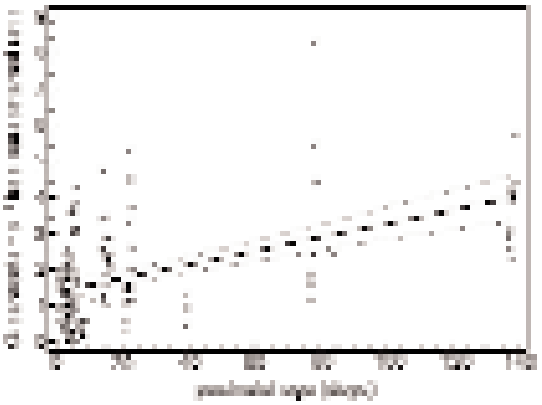


Figure 2: Linear regression analysis of postnatal age on urinary glucuronide-paracetamol/free paracetamol ratio (r= 0.2, 95% CI 0.17-0.45) (adapted from Allegaert et al. in press).

References are available on request: editorial@icu-management.org

Remifentanil use in the ICU: a health economic viewpoint

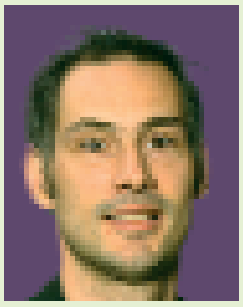
Due to its unique pharmacokinetic profile, remifentanil may lead to improved clinical outcomes and cost-savings in the Intensive Care Unit (ICU).

Abstract

Unlike other opioids, remifentanil is quickly metabolised to an inactive metabolite by non-specific esterases. It does not accumulate and has a very short context-sensitive half-life. Furthermore, the level of analgesia can be quickly increased to prevent additional pain associated with ICU procedures. The unique pharmacokinetic profile of remifentanil enables optimised sedation, better neurological assessment and faster post-infusion respiratory function recovery. Furthermore, the rapid and predictable offset of effects allows patients to be weaned and extubated faster. Decreasing time on mechanical ventilation may also minimise the risk of ventilator-associated morbidity. Although remifentanil is a more expensive option, it is inappropriate to consider health economics by comparing the net costs of drugs alone. Resource utilisation and attributable health effects must be taken into account to calculate the incremental net costs and effects. At this time, there are no published economic evaluations on the use of remifentanil in the ICU. However, several studies show that remifentanil can substantially decrease the length of ICU and hospital stay, so that its use may be cost-effective or even cost-saving, depending on the setting, country and perspective.

Introduction

A combination of sedation and analgesia is often required in critically ill patients, since they experience pain, anxiety, agitation and confusion, mostly related to painful procedures. One of the major reasons for patients being admitted to the ICU is the need for mechanical ventilation. Since 2002, remifentanil has been approved for the provision of analgesia in mechanically ventilated adult ICU patients by the European Medicines Agency. This paper summarises the available evidence on the use of remifentanil in the ICU from a health economic viewpoint.



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Pharmacokinetic profile

Remifentanil can be distinguished from other opioids by its unique pharmacokinetic profile. Non-specific blood and tissue esterases rapidly metabolise remifentanil to a clinically inactive compound. As a result, remifentanil does not accumulate and its context-sensitive half-life is about 3-5 min, independent of the infusion duration (Egan et al. 1993; Kapila et al. 1995; Malbrain et al. 2004; Westmorland et al. 1993). Additionally, remifentanil also has a rapid onset of action (1 min) reaching steady state concentrations. The pharmacokinetics of remifentanil do not change in patients with hepatic (Navapurkar et al. 1998) or renal impairment (Breen et al. 2004; Pitsiu et al. 2004). In comparison, traditional opioids may lead to accumulation, unpredictable metabolism, active metabolites and prolongation of effect with increased duration of infusion.

Clinical advantages of remifentanil in the ICU

CLINICAL ADVANTAGES

Based on its unique pharmacological properties, remifentanil has both potential advantages and disadvantages. I discuss first the potential benefits.

Remifentanil provides rapid, reliable and easily titratable analgesia and patient comfort. The level of analgesia can be quickly increased to cover additional pain caused by ICU procedures. Remifentanil enables an optimised sedation, often without the need for hypnotics (e.g. propofol). As a result, the possible negative effects, especially of over sedation (respiratory depression, hypotension, bradycardia, immunosupression, venous stasis, increased time on the ventilator, increased time in the ICU, failure to recognise cerebral insult, possible cognitive dysfunction (Ramsay 2000)) and the associated costs can be minimised. The prevention of over sedation allows patients to be awake or easily awakened within the ICU. This enables improved communication and thus optimised neurological/analgesic assessment and patient co-operation during ICU procedures, which in turn can decrease the need for expensive diagnostics such as brain CT (Wilhelm et al. 2004). Optimised sedation and rapid, predictable offset of effect allow patients to be weaned and extubated more quickly (Wilhelm 2004). Decreasing time on mechanical ventilation may not only reduce ICU and hospital stay (Wilhelm 2004), but also minimise the risk of ventilator-associated morbidity, such as airway trauma or pneumonia (Cook et al. 1998). Several studies investigating the use of remifentanil in an open-label manner have shown that weaning and extubation times are substantially reduced (Karabinis et al. 2004; Malbrain et al. 2004; Matthey et al. 2004; Matthey et al. 2004). Dahaba showed this effect even in a double blind study (Dahaba et al. 2004).

Table 1: Drug costs of analgo-sedation of a 70 kg patient according to a Belgian hospital*

	◊ml/h	mg/h	Cost/day (no hypnotic)	Propofol 2% 0.5mg/kg/h	Propofol 2% 1mg/kg/h	Propofol 2% 1.5mg/kg/h	Propofol 2% 2mg/kg/h	Propofol 2% 3mg/kg/h
ml/h				**1.75**	**3.5**	**5.25**	**7**	**10.5**
cost/day no opioid				17.2	34.3	51.5	68.7	103.0
Remifentanil**								
- 0.05µg/kg/min	**2.1**	**0.21**	32.0	49.2	66.3	83.5	100.7	135.0
- 0.1µg/kg/min	**4.2**	**0.42**	64.0	81.2	98.3	115.5	132.7	167.0
- 0.15µg/kg/min	**6.3**	**0.63**	96.0	113.1	130.3	147.5	164.6	199.0
Sufentanil								
- 0.25µg/kg/h	**0.35**	**0.0175**	10.6	27.8	45.0	62.1	79.3	113.6
- 0.5µg/kg/h	**0.7**	**0.035**	21.2	38.4	55.6	72.7	89.9	124.3
Fentanyl								
- 5µg/kg/h	**7**	**0.35**	25.5	42.7	59.9	77.0	94.2	128.6
- 8µg/kg/h	**11.2**	**0.56**	40.9	58.0	75.2	92.4	109.5	143.9
Alfentanil								
- 20µg/kg/h	**2.8**	**1.4**	17.7	34.9	52.1	69.2	86.4	120.8
- 50µg/kg/h	**7**	**3.5**	44.3	61.5	78.7	95.8	113.0	147.3

**Note: 2005 price levels; drug costs can vary between countries and settings*

Cost/ampulla:	*Remifentanil 5mg*	*31.734 Euros*
	Propofol 2% (20mg/ml-50ml)	*19.97 Euros*
	Sufentanil (50µg/ml-5ml)	*5.858 Euros*
	Fentanyl (50µg/ml-10ml)	*1.07 Euros*
	Alfentanil (500µg/ml-10ml)	*2.638 Euros*

***Remifentanil 100µg/ml*

Clinical disadvantages

Compared to other opioids there is only one clinical problem with the use of remifentanil and this can easily be solved. Owing to the rapid offset, the anaesthetist must plan the patient's analgesic requirements before remifentanil is discontinued. For some patients high dosages may also be necessary, possibly due to the phenomenon of opioid tolerance, which can occur with all opioids. Remifentanil, like other opioids, should be used with caution in patients with pre-existing sinus node dysfunction and/or arrhythmias, as it can cause bradycardia. When given in combination with anti-hypertensive drugs or to patients with severely depressed cardiac function, remifentanil should not be titrated above 0.25 mg/kg/min. In these patients the combination of remifentanil with midazolam may be preferable to propofol.

Health economics

Based on the above listed pharmacokinetic properties and clinical advantages, it is clear that the use of remifentanil has the potential to become the first choice agent for sedation and analgesia in the ICU.

As remifentanil is more expensive than other opioids its use may be anticipated to result in increased net hospital costs. However, the average remifentanil concentration required in the ICU is much lower than in the operating theatre (0.10-0.15 µg/kg/min versus 0.25µg/kg/min) (Dahaba et al. 2004; Muellejans et al. 2004). Table 1 lists the costs in a Belgian hospital for different treatment regimes at different doses for a hypothetical patient weighing 70kg. Remifentanil can also reduce the expense of hypnotics, as it has a hypnotic sparing effect. Consideration of drug costs alone is inappropriate because it doesn't take into account the changes in other cost types. A full economic evaluation, i.e. a cost-effectiveness analysis, is necessary to estimate the net costs and effects. Firstly, the resource utilisation and health effects of a remifentanil regime and of an appropriately comparable regime need to be measured in

detail and evaluated from a specific perspective (e.g. hospital, insurance or society). Secondly, the rendered costs and effects of the two regimes should be subtracted from each other to obtain the incremental net costs and effects. Dividing the gained net costs by the net effects produces the incremental cost-effectiveness ratio. Potential savings with remifentanil are likely to be gained by reducing the length of ICU and hospital stay and decreasing the risk for costly complications (pneumonia and antibiotics use). Optimised sedation may also lead to savings due to the prevention of diagnostic and medical procedures. Furthermore, the use of remifentanil could potentially result in improved health effects, decreasing the risks associated with over sedation, especially with long-term ventilation, which in turn may minimise the risks for negative sequelae.

Although economic evaluations are increasingly common in the critical care literature, such evaluations face several challenges and the reported approaches to their conduct are not standardized (American Thoracic Society 2002). At this time there is no published economic evaluation for the use of remifentanil in the ICU. Clearly, it will depend on the country and setting whether the use of remifentanil and the associated changes in hospital resource utilisation results in net costs or net savings to the specific payer, such as the hospital (Welte et al. 2004).

Conclusions

Owing to its unique pharmacokinetics, remifentanil has the potential to decrease the time on mechanical ventilation and the length of stay in the ICU and the hospital, and to minimise the use of expensive diagnostics. The cost-effectiveness of remifentanil in the ICU remains to be determined. For this purpose, a full economic evaluation from a specific perspective is necessary, to identify the incremental net costs and effects of remifentanil use compared to an appropriately comparable treatment.

References are available on request: editorial@icu-management.org

Patient-Controlled Analgesic infusion pumps

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 health care with over 240 employees globally. ECRI's focus is medical device technology, health care risk and quality management, and health technology assessment. It provides information services and technical assistance to more than 5,000 hospitals, health care organizations, ministries of health, government and planning agencies, voluntary sector organizations and accrediting agencies worldwide. Its databases (over 30), publications, information services and technical assistance services set the standard for the health care community.

The Healthcare Product Comparison System

Amongst its many products and services ECRI is pleased to provide readers of **ICU Management** with sample information on patient-controlled analgesic (PCA) infusion pumps 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. This extract from our database contains model by model specifications for easy assessment and review. The PCA Infusion Pump 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 26-28

[1]These recommendations are the opinions of ECRI's technology experts. ECRI assumes no liability for decisions made based on this data. [2]bolus demand, deliveries. Infused volume and volume remaining also displayed. [3]These increments refer to IV, epidural, and subcutaneous infusions, respectively; mg and µg equivalents are also available. [4]Stores history of amount and time given, history review hour by hour, and loading and clinical dosage amount and time given. [5]External battery pack also available. [6]6060 pain kit includes: PCA cord, 250 locking bag cover, two 9V batteries, and operators manual. [7]External rechargeable battery pack. [8](100/250/250E/500) [9]Keypad prompts, security code, integral locking-bag reservoir, and locking pole clamp. Pump detects when lockbox is unlocked and records the event in history. [10]pump tube only [11](50/100/150/200/300) [12]Two 1.5 V AA alkaline or lithium batteries; two 1.2 V 600 or 800 mA/hr Ni-Cd rechargeable batteries. [13]plus Medibox. [14]With pole clamp. [15]IV bag (≤9,999 mL), prefilled syringe (30 mL). [16]Also total given and reservoir volume. [17]Medication cassettes, security shell. [18]Also pain scale, total given, reservoir volume, event log, pain scale log, and 48hr dosing history. [19]Software confirms program changes. Lock code can be customized; extension sets with antisiphon valves.

Health care Product Comparison System

		ECRI RECOMMENDED SPECIFICATIONS[1]	ALARIS	BAXTER
MODEL		**PCA INFUSION PUMPS**	**PCAM SYRINGE PUMPS**	**6060 MULTI THERAPY**
WHERE MARKETED			Worldwide, except USA	Worldwide
FDA CLEARANCE			No	Yes
CE MARK (MDD)			Yes	Yes
CONFIGURATION		Any	IV-pole mounted	Patient worn or IV mounted
PCA DOSE BUTTON LOCATION		Bolus cord or pump	Bolus cord	Pump keypad, bolus cord
RESERVOIR	**Type (volume, mL)**	Any (≥30)	Syringe from 20-100 cc	Locking bag cover (250)
	Configuration	Any	Syringe	Fluid bag
	Access	Key, lockbox	Lockbox	Key
DISPLAY TYPE		LCD or LED	Not specified	Backlit LCD
	Data displayed	Dose, concentration, lock-out interval, rate, patient requests, alarms	History, start/stop, time, amount/ drug infused, pattern of use, events	Infusion rate, mode and status, alarms, event history[2]
CONTROLS	**Type**	Keypad preferred	Touch keypad	Membrane keypad
	Access	Key or security code	Self-prompting	Self-prompting
PUMPING MECHANISM		Any	DC motor and lead screw	Rotary peristaltic
ACCURACY, %		5	2	6
CONTINUOUS FLOW			0-90 µg/hr, 0.1-99.9 mg/hr	0.1-50 mL/hr
	Increments, mg/hr or mL/hr	0.1 mL/hr or equivalent mg or µg	10 µg/hr or 0.1 mg/hr	0.1 mL/hr, 0.1 mg/hr, 1 µg/hr
LOADING DOSE		Yes	0.1-99 mg	Yes
BOLUS DOSE		Yes	Yes	Yes
	Increments	0.1-25 mL	0.1-99.9 mg in 0.1-1 mg steps	0.1-50 mL, 0.1-25 mL, 0.1-0.5 mL[3]
DOSE PROGRAMMED		Yes	Yes	Yes
	Concentrations	0.1-100 mg/mL	mg/mL, µg/mL	0.1-99.9 mg/mL, 1-1,000 µg/mL
LOCKOUT INTERVAL RANGE, min		≤5-100	0-180	1-720
MRI COMPATIBLE		Desirable	No	No
ALARMS/INDICATORS		Air-in-line, near end of infusion, empty, low and depleted battery, occlusion, online or battery power	Syringe almost empty; syringe empty; cover open; battery low and exhausted; patient handset removed; power failure (opt); max dose; internal malfunction; drive disengaged; nurse attention	Air-in-line (0.1, 0.5, 2 mL, disabled); low bag; infusion complete; low/empty battery; cassette not installed; door open; upstream occlusion (on, disabled); downstream occlusion (high, low); infusing; hold; callback alert; internal malfunction
FREE-FLOW PROTECTION		Yes	Not specified	Set based, clamp
ACCUMULATED DOSE LIMIT		Yes	1-999 mg over 8 hr in 1 mg steps	100 mL/hr up to 999 mL in 12 hrs
SAFETY FEATURES		Lockbox, locking keypad, memory protection, tamper evident	Lockbox	Lockout (3 levels), lock box (2 sizes), locking softpack, "total allowed" limit, visual and audible alarms, configurable limts (units, modes, dose)
EVENT LOG		Yes	Yes	Yes
	Display	Yes	Yes	2-line, 16-character
	Printout	Yes	Yes	NA
	Number of events	≥200	Not specified	Depends on use
	Time retained	1 year	Not specified	Depends on use
	Data stored	Event history, drug infused, settings, alarms	Time, event, total drug infused, settings	Patient bolus requests, boluses given, average time between boluses[4]
BATTERY TYPE/NUMBER		Any common type	Sealed lead-acid/ not specified	9 V alkaline (or lithium)/2[5]
	Life, hr	Varies w/infusion	15	40 @ 50 mL/hr
	Recharge time, hr		24	24 hr
LINE POWER, VAC			110-120, 220-240, 50/60 Hz	110/220 (battery eliminator)
H x W x D, cm (in)			11.5 x 40 x 18 (4.5 x 15.7 x 7.1)	11.9 x 9.9 x 5.8 (4.7 x 3.9 x 2.3)
WEIGHT, kg (lb)			3.8 (8.4)	0.45 (1) w/batteries
PURCHASE	**List price - Unit**		Not specified	$4,200 (pain kit)[6]
	- Set		Not specified	$17.25
	- Reservoir		Not specified	Included w/pain kit
	- Battery		Not specified	$95[7]
	Warranty	Yes	2 years	1 year
OTHER SPECIFICATIONS			None specified.	Customizable programming sequence; configurable rate & volume upper limits; clinician dose; configurable bolus rate.

BAXTER	BAXTER	DEBIOTECH	FRESENIUS	PEGASUS
IPUMP	**PCA INFUSOR W/PT CONTROL MODULE**	**CHRONOPUMP IV EXPRESS**	**MASTER PCA PACK**	**PEGASUS VARIO PCA**
Worldwide	Worldwide	Worldwide	Worldwide, except North America	Worldwide
Yes	Yes	Yes	No	No
Yes	Yes	Yes	Yes	Yes
Ambulatory (carrying bag), locks to IV pole	Patient worn	Not specified	Locks to IV pole, tabletop	Patient worn, locked to IV pole
PCA cord, pump keypad (if configured)	Patient control module	Not specified	Waterproof bolus cord	Pump, optional bolus cord
Locking bag cover[8]	Baxter (60)	Not specified (50, 100, 150, 200)	Syringe (20, 50/60)	Polyurethane bag[11]
Fluid bag, bottle	Inflatable balloon	Standard bag	Syringe	Disposable bags
Key	back-check valve	Not specified	Key	Lockbox
Backlit LCD	None	LCD	Graphic LCD	LCD
Programming steps, alarm status, Rx & PT history, power/therapy status...	NA	User prompts, VTBI, rate, time, alarms, history, reservoir volume...	Comprehensive messages and trends	Infusion amount, volume remaining, time bolus demand, time, date, alarms
See footnote[9]	Push button	Keypad	Rotary knob, keypad	Softkey
See footnote[9]	NA	Code lock	Electronic key, security code	Self-prompting
Linear peristaltic	Elastomeric balloon	Satellite peristaltic	Stepper motor, lead screw	Micro double piston
8	10	5	2 drive accuracy	2
0.1-90 mL/hr	No	Not specified	0.1-800 mL/hr, 0.001-99.9 mg/hr	0.01-15 mL/hr or 0.01-999 mg/day
0.1 mL/hr, 0.01 mcg/ hr, 1 µg/hr	NA	Not specified	0.1 mL/hr, 0.5 µg/hr	0.1 mL/hr
0-49.9 mL	No	Not specified	0.001-99.9 mg	Yes
0-49.9 mL	Yes	Not specified	0.001-99.9 mg	0.1-99 mL
0.1 mL/hr	0.5 mL/dose (fixed)	Not specified	0.5 µg, 1 µg, 0.1 mg	0.1 mL
Yes	No	Yes	Yes	Yes
mg/mL, µg/mL	NA	Not specified	0.001-99.9 mg/mL	Yes
1-60/1 hr;1-240/4 hr	6, 15, 60	Not specified	1-120	1-1,439
No	Not specified	No	Not specified	No
Up and downstream occlusion; air-in-line; fluid volume low; bag empty; PCA button missing; sys malfunction; bag cover unlocked; low or depleted battery; AC adapter; stuck PCA button/key; check tubing placement; left in programming mode; 1 or 4 hr limit reached	Bolus-ready indicator tabs on wristwatch; volume indicator	Occlusion; air-in line; infusion near end; reservoir empty; system malfunction; low battery; audible and visual indicators with temporary alarm silence	Audible alarm; LED and LCD graphics and messages; bolus ready; <1 bolus dose or <15 min contin infusion; remaining volume; infusion end; bolus/patient-demand trends; infusion pressure; pusher not engaged; incorrect syringe insertion; unauthorized entry attempt	Low or depleted battery and residual volume; occlusion; system malfunction; door open; air-in-line has been filtered out w/o an alarm; no air infusion possible
Anti-siphon valve	Not specified	Yes	Not specified	Yes
90 mL/hr total	0.5, 2, or 5 mL/hr	Not specified	0.01-9,999 mg over 1-12 hr	4 and 8 hrs
Configurable limits (units, infusion modes, max PCA dose, max basal rate, max bolus dose), 3 configurable safety modes, visual & audible alarms	Not specified	Not specified	12 hr limit, program-access electronic key, lockable cover, limit dose, occlusion and line-disconnection alarms	Lockable med reservoir, locking keypad (3 levels), patient line w/normally closed check valve and air-eliminating filter, self-tests, 65 dB audible alarms
Yes	No	Yes	Yes	Yes
Yes	NA	Yes	Yes	Yes
Yes	NA	Yes	Yes	Via computer
400	NA	1,000	1,500	1,000
Unlimited/batt fail	NA	Not specified	Indefinitely	Indefinitely
Cover unlocked, start/stop, bolus start/infused, dose limit reached, end, alarms, Rx changes	NA	Settings, alarms, program changes, events	Parameters and changes, time demand, doses, demand attempts	Settings, alarms, errors, changes, malfunctions, bolus demand and deliveries
9 V/1	None, positive pressure creates flow	7.5 V Ni-MH internal	Sealed lead-acid/ not specified	See footnote[12]
80 @ 10 mL/hr	NA	12-24	7	20 @ 15 mL/hr
NA	NA	5 max when in use	16	5
100-120, 50/60 Hz	None, positive pressure creates flow		110/120, 220/240	220
8.7 x 12.4 x 4.6 (3.4 x 4.9 x 1.8)	16.5 x 3.3 (6.5 x 1.3) diameter[10]	14 x 5.9 x 4.2 (5.5 x 2.3 x 1.7)	13.5 x 37 x 24 (5.3 x 14.6 x 9.4)	8.3 x 6.2 x 3.1 (3.3 x 2.4 x 1.2)[13]
0.45 (1)	0.005 (0.01) empty[10]	0.4 (0.8)	4.1 (9)	0.15 (0.33) with batteries
$4,295	$45	Not specified	Not specified	Not specified
$8.50	Not specified	Not specified	Not specified	Not specified
250E lockbox incl	Not specified	Not specified	Standard syringe	Not specified
Off shelf 9 V	NA	Not specified	Not specified	Not specified
1 yr included, extended available	NA (disposable unit)	1 year	1 year	3 years
Configuration can be transferred from 1 pump to multiple additional pumps; choice of security types & infusion modes; patient history can be printed for records; security codes can be changed; re-alarm if not attended in 2 min; occlusion & air detection. UL listed.	Optional IV pole and/or bedpost mount; entire system is disposable.	Multiple accessories for hospital, alternate site, and home-care use.	Programmable in mg or µg; RS232 interface; printer/PC download; titration mode; 5 PCA modes; PCA/PCEA protocol library; includes a standard infusion pump; antisiphon valve on extension set.	Continuous, PCA, or circadian infusion; telemetric programming (IR or RF); multilingual text display available; real-time clock; includes intrathecal, epidural, IV, and subcutaneous applications.

Health care Product Comparison System

		SMITHS MEDICAL GRASEBY MEDICAL	SMITHS MEDICAL DELTEC	SMITHS MEDICAL DELTEC
MODEL		**3300**	**CADD LEGACY PCA MODEL 6300**	**CADD-PRIZM PCS II**
WHERE MARKETED		Worldwide	Worldwide	USA
FDA CLEARANCE		Yes	Yes	Yes
CE MARK (MDD)		Yes	Yes	Yes
CONFIGURATION		IV mounted	Pole-mount bracket (can lock to IV pole), ambulatory	Pole-mount bracket (can lock to IV pole), ambulatory
PCA DOSE BUTTON LOCATION		Handset	Pump, optional remote dose cord	Remote dose cord
RESERVOIR	**Type (volume, mL)**	Syringe (20, 30, 50)	See footnote[15]	See footnote[15]
	Configuration	Syringe	Cassette or IV bag[15]	Cassette or IV bag[15]
	Access	Key	Key	Key
DISPLAY TYPE		LCD	LCD	LCD
	Data displayed	Infusion amount, bolus demand and deliveries, alarms, event history	Units, conc, rate, dose, dose limits, doses given, dose attempted[16]	Units, conc, rate, dose, dose limits, doses given/attempted/last cleared[18]
CONTROLS	**Type**	Touch-control keys	Softkey	Softkey
	Access	Self-prompting	Operational code	Operational code and/or key
PUMPING MECHANISM		Lead screw	Linear peristaltic	Linear peristaltic
ACCURACY, %		2	6	6
CONTINUOUS FLOW		0.1-20 mL/hr w/bolus, 0.1-99.9 mL/hr	0-50 mL/hr	0-30 mL/hr
	Increments, mg/hr or mL/hr	0.1 mL/hr or 1 µg/hr	0.1 mL/hr	0.1 mL/hr
LOADING DOSE		Yes	Without stopping	Without stopping
BOLUS DOSE		Yes	0-9.9 mL	0-9.9 mL
	Increments	0.001-99.5 mg/mL	0.05 mL/hr	0.05 mL/hr
DOSE PROGRAMMED		Yes	Yes	Yes
	Concentrations	0.001-99.5 mg/mL	0-100 mg/mL, 0-500 µg/mL	0-100 mg/mL, 0-500 µg/mL
LOCKOUT INTERVAL RANGE, min		0-360	5-1,440	5-1,440
MRI COMPATIBLE		No	No	No
ALARMS/INDICATORS		Nearly empty; low battery; on battery; occlusion; dose limit exceeded; pump stopped; cover not closed; syringe not fitted correctly; internal malfunction	Low or depleted battery; low or depleted residual volume; high pressure; pump fault; upstream occlusion; air- in-line; cassette detached/attached	Low/depleted power status; low/depleted reservoir volume; cassette detached/ attached; high pressure; upstream occlusion; pump fault; air-in-line; print failure
FREE-FLOW PROTECTION		Not specified	Yes	Yes
ACCUMULATED DOSE LIMIT		1-8 hr	0-12 doses/hr	0-12 doses/hr, delivery limit
SAFETY FEATURES		Locking keypad, self-test, 1-8 hr limit, 3 types of audible alarms (insistent, fault, noninsistent), program/ memory protection	3 programmable lock levels, CADD extension sets with antisiphon valves, cassette detection, upstream occlusion[17]	3 programmable lock levels, auto-lock, medication cassettes & security shell, cassette & upstream sensors[19]
EVENT LOG		Yes	Yes	Yes
	Display	4-line, 20-character	Doses and attempts	Doses and attempts
	Printout	Yes	Via PC program	Printer or computer
	Number of events	1,500	1,000	500
	Time retained	Not specified	Indefinitely	Indefinitely
	Data stored	Amount delivered, configuration parameters, number of patient demands, event history	Most recent 1,000 events	Most recent 500 events or last 48 hr dosing history by hour, pain scale
BATTERY TYPE/NUMBER		Sealed lead-acid/ not specified	AA alkaline/2	9 V alkaline/lithium/1
	Life, hr	8	336 @ 10 mL/day	120 @ 10 mL/hr
	Recharge time, hr	12	NA	Not specified
LINE POWER, VAC		100-120 or 220-240 @ 50/60 Hz	120/230/100	120/230
H x W x D, cm (in)		13 x 33.5 x 19.5 (5.1 x 13.2 x 7.7)[14]	11.1 x 8.9 x 3.0 (4.4 x 3.5 x 1.2)	4.4 x 10.4 x 14.1 (1.7 x 4.1 x 5.6)
WEIGHT, kg (lb)		3.5 (7.7) including batteries[14]	0.34 (0.75)	0.57 (1.25)
PURCHASE	**List price - Unit**	Not specified	$3,595	$4,125
	- Set	Not specified	$171 for 12	$171 for 12
	- Reservoir	Not specified	$171 for 12	$171 for 12
	- Battery	Not specified	Not specified	Not specified
	Warranty	3 years	1 year	2 years
OTHER SPECIFICATIONS		Rolling buffer stored in event log. TGA & TUV approved.	Real-time clock; programmable in mg, µg, mL; titratable; indications include IV, subcutaneous, epidural, & subarachnoid space infusions; on/off key; biomed functions for customization.	Real-time clock; programmable in mg, µg, or mL; IV, subcutaneous, epidural, & subarachnoid indications; biomed toolbox for customization (PCS plus custom lock code, max bolus delivery rate); titration limits; PC-based protocol library.

Continuous regional analgesia

Dr Casati and colleagues review the potential of regional analgesia in the management of trauma and post-surgical patients in the ICU.

Regional anaesthesia/analgesia techniques

Regional analgesia (RA) techniques (including spinal, epidural and peripheral nerve block techniques) are effective not only in optimizing pain control, but also in reducing stress responses associated with surgery, and with clinically relevant effects on short- and long-term recovery after major surgery (Carli et al. 1995; Carli and Halliday 1996; Holte and Kehlet 2002). Routine use of a protocol-driven light sedation results in better physical and psychological outcomes in ICU patients, especially when daily awake times are granted (Kress et al. 2000). Moreover, although large randomized controlled trials are still ongoing, there is increasing evidence of the benefit of early tracheotomy in patients estimated to require intermediate to long-term ventilation, while non-invasive ventilation is increasingly used both inside and outside the ICU (Keenan et al. 2004). Guidelines from the Society of Critical Care Medicine (SCCM) recommend pain control and sedation to improve psychological and physiological variables ranging from sleep deprivation to myocardial oxygen consumption (Jacobi et al. 2002). Regional analgesia techniques have been excluded from analysis, although the adverse effects of systemic opioids and other analgesics are acknowledged. As changes in critical care practice are introduced in the daily clinical routine, clinicians may be faced with the problem of providing effective pain control in a lightly sedated or even fully awake patient.

Route of administration for prolonged RA techniques

All RA techniques can be performed using either bolus or continuous drug administration, although safety of continuous intrathecal anaesthesia has not yet been demonstrated for continuous administration (Denny and Selander 1998). Prolonged RA techniques usually involve the insertion of catheters for repeated or continuous drug administration at the selected site, and may therefore be considered as "minimally" invasive techniques.

Central nerve block techniques, including epidural analgesia, may potentially increase the risk of spinal haematoma, which may be increased during anticoagulation therapy and/or in conditions affecting coagulation, such as trauma or sepsis. Consensus statements for the general surgical population have been published by both the American and European societies for regional anaesthesia (Horlocker et al. 2003). In general, abnormalities of prothrombin time, activated partial thromboplastin time and/or platelet count are risk factors for epidural haematoma. Practice parameters are suggested for patients undergoing anticoagulant therapy, such as placing the central block 12 hours after and 2 hours before a dose of low-molecular weight heparin. Continuous peripheral nerve blocks (CPNBs), where applicable, could represent a safer alternative in patients with intractable coagulation abnormalities.

Multiple drug-resistant pathogens are often found in ICUs, so that the risk of contamination of the entry site and subsequent soft-tissue with indwelling catheters must be considered, and the risk of infection of peripheral or the central nervous system. In an analysis of 75 ICU patients receiving epidural analgesia for a median of 4 days, Darchy and colleagues (1996) reported that 36% developed local signs of inflammation (erythema and/or local pus discharge), and 12% had positive cultures at the insertion site (Darchy et al. 1996). No neurological or systemic complications were seen, and there was no significant association between local erythema and subsequent infection, suggesting that erythema alone is not an indication for catheter removal. Interestingly, the colonization rate in ICU patients was lower than that reported in the general hospital population (15% versus 20-28%) as reported in large series (McNeely et al. 1997; Simpson et al. 2000). This might be related to the extensive use of antibiotic prophylaxis reported in the ICU setting.

Peripheral nerve catheters seem to be associated with a lower risk of local infection, at least in the general hospitalized population. The incidence of signs and symptoms of local infection in two large series of axillary and brachial plexus block ranges from 0.2% to 0.8%, with no systemic infection reported (Bergman et al. 2003; Borgeat et al. 2003). From a theoretical viewpoint, a catheter placed for lower-limb blocks at the gluteal or inguinal level might be considered at higher risk of contamination and colonization. In an analysis of 208 femoral catheters placed for postoperative analgesia in orthopaedic patients, Cuvillon and colleagues found a colonization rate of 57.0% at 48 hours (Cuvillon et al. 2001). Local infection was investigated by ultrasonography, and no abscesses or cellulitis were found. The authors report three (1.4%) "signs" of sepsis, which spontaneously resolved after catheter removal.

Several techniques have been proposed to reduce colonization and infection rates, including specific disinfectants (Birnbach et al. 2003), entry-site dressings (Shapiro et al. 1990), tunnelling of perineural catheters (Boezaart 2002) and intensive nursing care of the catheter. In the absence of specific information on ICU patients, exten-

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sive colonization control should be weighed against a relatively low risk of clinically significant infection, increased patient discomfort and increased nursing workload.

Dosing regimens

There has been much debate as to the most effective technique for administering RA in a variety of settings.

Continuous thoracic epidural analgesia (TEA) and paravertebral blocks (PVB) have been evaluated in chest trauma patients (Karmakar and Ho 2003). Only the use of central or peripheral nerve blocks with local anaesthetic (LA) has been demonstrated to improve respiratory variables (Karmakar and Ho 2003) and pain control (Worthley 1985), and reduce ventilation-dependent days and hospital stay (Karmakar and Ho 2003). Significant results have been obtained using either continuous infusions or intermittent boluses administration.

Patient-controlled RA (PCRA), with either a minimum infusion rate or only patient-controlled boluses, seems to be the most efficient approach to pain management in general surgical populations. Advantages include equivalent or improved pain control (Lubenow et al. 1994; Singelyn et al. 1999) with reduced LA consumption and complications (Eledjam et al. 2002; Standl et al. 2003).

If an ICU patient is awake and able to understand and cooperate, he or she could effectively operate a PCRA device; however, in the routine ICU setting, patients usually need at least a light sedation to tolerate the endotracheal tube and/or synchronization with a mechanical ventilator, and this clearly interferes with accurate patient pump control.

An advantage of PCRA is the possibility of objectively weighting patient discomfort throughout the treatment by calculating the ratio between delivered and requested boluses. This index is less precise than direct scoring of pain intensity with visual analogue pain scales (VAS) or numerical rating scores (NRS); however, it does not depend on the patient's ability to communicate. Pain measurement tools based on behavioural and physiological variables have also been developed and validated in the post-anaesthesia care unit population (Mateo and Krenzischek 1992; Puntillo et al. 1997), and are currently recommended by the SCCM in patients who are not able to communicate (Jacobi et al. 2002). Although they take longer to measure, these scales may be useful for patients who are not able to communicate or activate patient-controlled RA devices.

Cognitive dysfunction commonly occurs in the ICU, as a result of direct brain trauma or secondary to other conditions, and may prevent the patient from effectively understanding instructions, or performing even simple purposeful actions, such as pressing the bolus release button. In these cases, when appropriate, the clinician can simply switch the patient to a continuous-infusion RA, titrated to the behavioural/physiological pain response.

Nurse-controlled analgesia protocols have been successfully employed in the ICU setting in cardiac surgery patients, although studies are limited to intravenous analgesia. This technique has been shown to be inferior to patient-controlled analgesia (Pettersson et al. 2000), but may represent an alternative to continuous infusion for disabled patients. Existing protocols for nurse-controlled sedation could be modified to take into account patient pain, and to deliver RA. However, additional research is needed to assess efficacy and efficiency of this procedure, particularly as nurse-controlled analgesia increases staff workload.

It is our opinion that specific devices should be employed, whenever bolus modes are used. Patient-controlled infusion pumps are specifically designed to simplify the bolus delivery procedure, eliminating the requirement for the patient to be able to communicate with the nurse. Additionally, PCRA devices have lockout time and precise dose settings, decreasing excessive or imprecise dosage risks. They also reduce the need for catheter manipulation, reducing inadvertent removal or contamination risks.

Conclusions

Regional analgesia may be a valuable tool in the management of post-surgical or trauma patients in the ICU. Its benefits include improved comfort in the fully awake or lightly sedated patient, reduced opioid consumption with minimum effects on patient weaning, and reduced stress response to injury. These advantages should be weighed against the risk of infection and haemorrhage, especially when performing central blocks. Plasma levels of absorbed LA in patients with alterations of capillary permeability (sepsis, burns) should also be investigated, since high concentrations may lead to brain and myocardial toxicity. Future research should focus on the net impact of effective pain and stress control on outcome.

Dosing regimens for RA should be individualized. Patients who are able to operate the bolus release button are likely to benefit from PCRA techniques. The role of continuous, low-rate background infusion remains unclear, but it might be useful, as lightly sedated patients may have decreased responsiveness.

PCRA devices may be useful even when nurse or physician controlled intermittent analgesia is used, as they are more easily and safely operated. Nurse controlled analgesia protocols may be safer and more effective than continuous infusions titrated "as needed". However, these protocols are likely to increase staff workload, as effective pain assessment requires communication or the use of specific behavioural and physiological scales.

References are available on request: editorial@icu-management.org

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Continuous monitoring of ICU process quality

Management techniques already proven in commerce and industry are increasingly applied to health care. Professors Hiesmayr and Schmidlin provide an introduction to the application of industrial monitoring techniques to intensive care.

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Introduction

Intensive Care can be seen as serial and parallel processes with the goal of reaching the best possible outcome for the largest number of patients. We present and evaluate the differences between intermittent and continuous methods of process monitoring and propose adapting some methods commonly used in the manufacturing world for application to medical activities (Berwick 1996).

Process monitoring

Process monitoring (Hinckley 1997) started at the end of the 19th century and was originally based on judgement inspection. Skilled craftsmen reworked the products at the end of the production line until they considered them suitable for use. H. Ford introduced gage inspection, the comparison with a standard, (a first form of benchmarking), because he noted that variability between products was hindering continuous production. In the 30's Shewhart developed statistical process control with control charts, allowing detection of processes drifting out of control, using control limits at 3 standard deviations (SD) from the mean (Montgomery 1997). While this method is a compromise between detecting drifts and avoiding unnecessary warnings, it is ineffective for small drifts. Methods such as the cumulative sum chart (CUSUM) have therefore been introduced. Extremely efficient industries have introduced 100% inspection with source inspection and mistake proofing. This method is applicable to rare events, such as those occurring in intensive care, e.g. medication errors (Darchy et al. 1999), infections, failed extubations and death. This method is applied with checklists and has increased patient safety (Hinckley 2003). The major goal is prevention not observation and low investments in quality control are necessary.

Intensive care, with its large amount of data, is an attractive area in which to develop and refine various methods of process monitoring. Two factors are of major importance: events may be infrequent and it is highly desirable to detect deviations early (Harvey and Wensing 2003).

Definition of a process

A process is a defined activity to transform a given input, typically in medicine the patient with his/her clinical condition, into a desired state. Thus a process can be defined by the task to perform, the various inputs such as patients, human resources and capital, and the output of the process including its side effects.

Typically a process is evaluated by comparing the actual result with the expected result. In the field of intensive care, the inputs should also be monitored. A well known example is the relation between accepted mortality and physiological derangement early on after admission to ICU as defined by several scoring systems (SAPS II, SAPS III, MPM). Some inputs cannot be controlled easily and thus a risk adjusted evaluation of the process may be mandatory.

Monitoring of process quality

Two elements define quality: the difference between the mean value from the target and the variability of this mean. Variability is assessed with measurement of range or moving range, SD; for proportions a repeated determination is necessary. Deviations from the standard are not always symmetrical. An infection in the ICU necessitates many resources which are not compensated for by patients without infections. Losses have an irreversible character in medicine. In this sense many medical processes cannot be described by stock exchange processes, where losses are compensated by gains.

How to monitor a process

The information about a process is either a measurement or a count. Examples may be length of stay, duration of intubation, proportion of patients with nosocomial infections, proportion of patients with sufficient nutritional therapy or proportion of patients dying in hospital. Yearly intervals are the typical feature of many reports, but a similar mean value could represent different scenarios.

Thus a more detailed insight into the process over time is necessary. This can only be achieved by time series analysis.

Examples of continuous monitoring

CONTROL CHART

The control chart is constructed from the mean of a measurement or the observed proportion of events. Typically confidence limits are added to the chart at 3 standard deviations (SD) from the centre line. In certain

cases it may be helpful to introduce an early warning limit at 2 SD (Montgomery 1997).

As an example, Figure 1 illustrates monitoring with a target for nutrition care set at 22 Kcal/kg/day on the 5th day post admission in the ICU. The mean amount of nutrition given was derived from samples of 30 consecutive patients. The range was calculated as the mean absolute patient to patient difference for 30 consecutive patients. In 4 instances the lower 3 sigma limit was reached, often in conjunction with a higher patient to patient moving range. Corrective measures should first address the variability.

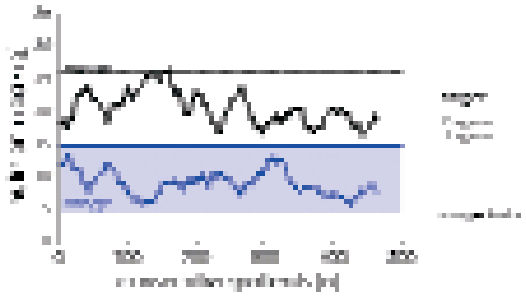

Figure 1: Control chart for nutrition care in the ICU

Cumulative sum chart with risk adjustment

The cumulative sum chart (CUSUM) is a sensitive instrument to detect small changes in process mean or proportions. The CUSUM detects shifts in performance smaller than one standard deviation of a sample. Each CUSUM starts with an estimation of the baseline event rate. When the event of interest (death, infection) does not occur, the difference between the predicted event rate and the observed event rate is equal to the predicted event rate. When the event of interest occurs, the difference between predicted and observed rate is the predicted rate minus one event. These values are now cumulated from one patient to the next. Figure 2 shows a baseline mortality rate set to 0.1; predicted survival = 1-predicted mortality; patient numbers 4 and 16 died and therefore have no predicted survival; encircled values are cumulated. The CUSUM also accommodates risk adjustment (Lovegrove et al. 1997; Sherlaw-Johnson et al. 2000).

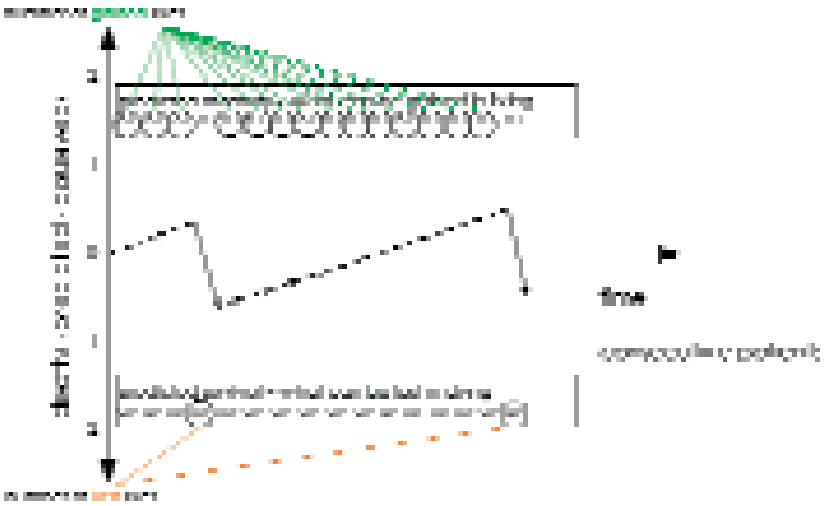

Figure 2: Cumulative sum chart for mortality

Pitfalls & challenges

We recommend starting from local data series to define the correct starting points. A data series from a sufficient duration should be used to determine a local standard. This standard should also be compared with external standards, if available. Thus new databases for quality control should include parameters with similar definitions to those already published, to allow external benchmarking. A major challenge is to choose control limits in such a way that a reasonable compromise between detecting drifts and avoiding unnecessary warnings is implemented.

Summary

Continuous process evaluation is a key element to guide improvements in health care. Continuous process control has the advantage of detecting deviations early and generating new information about the process, allowing learning from actual processes and outcomes. The vision is to evolve from the control of an isolated process to the integrated control of several processes so that information is presented as a common weighted risk management display, as applied in manufacturing and service industries.

References are available on request: editorial@icu-management.org

Nutrition management

Dr Wernerman reviews the limited current-day evidence to guide nutrition management for ICU patients.

Does good nutritional management make a difference?

Evidence for nutritional interventions in the ICU is unfortunately rather weak. Although there are many studies on nutrition in the ICU reported in the literature, most are of a poor quality or are inconclusive. This is not unique to nutrition, however, as demonstrated in a recent literature review by an expert panel in the Surviving Sepsis Campaign (Dellinger et al. 2004). This report demonstrated that very few modalities had sufficient scientific evidence for use. Many well established treatments, that are taken for granted, do not rest upon sufficient scientific evidence. So in clinical practice we are left with expert opinions and local traditions etc. Concerning nutritional management, it was therefore revealing when the evidence for an improved outcome following tight glucose control was published (Van den Berghe 2001). This single centre study demonstrated that tight glucose control using intensive insulin therapy resulted in improved mortality outcome. This study from Leuven, Belgium, has been discussed extensively ever since. Although not everyone regards the result as conclusive, and some find it controversial, the impact upon clinical practice has been tremendous. At present, in most European countries, avoiding hyperglycaemia or keeping blood sugar between 5 and 8, has become a general routine. So for this particular aspect, good nutritional management has made a difference.

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Controversies

Over the last 20 years there has been a very antagonistic controversy over the administration route for feeding ICU patients. In particular, spokesmen in favour of enteral nutrition point out that parenteral nutrition to ICU patients is expensive and dangerous (Marik and Pinsky 2003). The evidence for this standpoint, however, is not impressive. In the recently published Canadian guidelines (Heyland et al. 2003), a meta analysis reveals a difference concerning ICU morbidity in favour of enteral nutrition, and no difference in ICU mortality. However, most of the studies covered in the meta-analysis are small and dated. The most important quantitative evidence provided is from another meta-analysis which combined subgroups of patients from earlier studies during the 80's (Moore et al. 1992). A recent high quality study focuses on patients for whom functioning of the gastro-intestinal tract is uncertain (Woodcock et al. 2001). Although the number of randomised patients is small, the study clearly points to the principal difficulties. The enterally fed group was heavily underfed and had a higher mortality, although not statistically significant. The parenterally fed group was fed for a longer period of time, and the complication rate was related to the length of nutritional treatment. This finding is universal; the longer the feeding, the more complications, regardless of the route of feeding.

Another controversy is when to start feeding ICU patients. There is a strong trend, supported by evidence, that early enteral feeding promotes more successful feeding following elective surgery. This is particularly true for the enteral route. This notion has been adopted in the ICU without any solid evidence. Today's trend in both Europe and North America, therefore, is to start feeding ICU patients earlier, preferably by the enteral route. This practice needs to be substantiated by prospective studies concerning the risks and possible benefits.

Protocols

It has become more and more evident that a practical and strict protocol is needed to achieve successful feeding in the ICU, particularly by the enteral route. Prospective studies to document the beneficial effects of such a strict protocol are very problematic from a methodological point of view. Although not conclusive, there are studies, usually with historical controls, that report a lower mortality when such a protocol is in use (Martin et al. 2004). However, it is well known, from a large number of studies, that the success of enteral feeding is very low, due to supply of only 60-70% of the prescribed amount. This level of underfeeding is of course problematic, as there are also publications suggesting that a cumulative energy deficit in ICU patients is a pathogenetic factor for morbidity and even mortality (Barlett et al. 1982; Singer et al. 2004). For this reason, adherence to a rather strict nutritional protocol is advocated by most experts currently, although the evidence for this recommendation is not very solid.

Specific nutrients

A few years ago reports of advantageous effects from the use of immuno-nutrition in postoperative patients spilled over into the ICU. There are at present a large number of studies with elective surgery patients showing a lower rate of complications when immuno-nutrition is

used. Immuno-nutrition here means an enteral feed supplemented with excessive amounts of arginine, omega-3 fatty acids and nucleotides. The recommendation is substantiated by several meta-analyses (Beale et al. 1999; Heyland et al. 200; Heys et al. 1999). However, there is no evidence to substantiate this for ICU patients. One meta-analysis even shows that there may be dangers involved in administrating such formulas to ICU patients (Heyland et al. 2001). Overall there is no meta-analysis demonstrating any difference in mortality or morbidity in ICU patients. There are, however, attempts to find subgroups of ICU patients where the use of enteral immuno-nutrition may be recommended, in spite of the marginal benefit documented (Proceedings from Summit on Immune-Enhancing Enteral Therapy 2000). The place for these immune enhancing feeds in the ICU is not established and remains controversial.

Another nutritional additive in ICU nutrition is glutamine. Conventional intravenous formulas do not contain glutamine, since glutamine is unstable in aqueous solution. As the dipeptide technique has now overcome this difficulty, the addition of glutamine supplementation to intravenous feeding has resulted in prospective clinical trials. These show a clinical benefit in terms of mortality for ICU patients (Goeters et al. 2002; Griffiths et al. 1997; Novak et al 2002) and there are now ongoing studies in larger patient populations. The present standpoint is that intravenous glutamine supplementation may be advantageous, it is expensive, but it is not associated with harmful effects. Addition of enteral glutamine is less well supported by evidence, but may be useful in subgroups of patients.

Conclusion

Nutritional management in the ICU should follow a strict routine in the individual units. Most centres use the combination of enteral and parenteral feeding to reach the nutritional target, which is usually the estimated energy expenditure of the patient. Today calorie intake tends towards the low side, rather than high. These routines should also contain registration of all nutrition related complications, to minimise complications and avoid outweighing the beneficial effects of nutrition. Good hygiene routines for venous lines and feeding tubes are essential and elementary. This should be combined with a tight glucose control to avoid hyperglycaemia and glutamine supplementation, at least for the group of patients dependent mainly upon parenteral nutrition.

References are available on request: editorial@icu-management.org

Step down wards: advantages and disadvantages

Professor Burchardi shares his views on step down wards with ICU Management readers.

Step down wards are care units between the level of an intensive care unit and the normal ward. Various types are possible: the intermediate care unit (IMC), post operative monitoring (recovery), but also units for coronary care, non-invasive ventilation, long-term ventilation etc.

I will restrict my comments to only the IMC, which is closely linked (as the name indicates) to an intensive care unit (ICU); its purpose is the pre and post intensive care (or instead of intensive care). So it offers a buffer capacity for the ICU – an important way to relieve the pressure on precious and costly ICU beds. However, it is difficult to describe exactly the criteria where intermediate care ends and intensive care begins – presumably this depends greatly on the given structure of the hospital (for example, the quality of care in the normal wards). The most simple criteria could be any actual treatment of life-threatened vital functions, (for example, mechanical ventilation), which by definition is the privilege of intensive care medicine.

In an editorial, Professor J.-L. Vincent and I recommended a mixed model, where within the same unit intensive care and intermediate care beds are jointly available (Vincent and Burchardi 1999).
Some of the important advantages of such a mixed structure are:
(a) same, experienced nursing staff, with high attention to potential medical problems;
(b) release from the high work load of nursing exclusively critically ill patients;
(c) no lack of information, if the patient suddenly needs intensive care;
(d) no transport to an ICU located elsewhere;
(e) IMC beds as buffer capacity for the ICU beds.

This last point is most important: the precious, most costly ICU beds can be managed much more adequately and efficiently if there is a buffer with IMC beds. The relation between ICU beds and IMC beds in such a unit should be variable and adapted to the actual needs.

We have used such a mixed model in an 18 bed surgical ICU. However, from our practical experiences some important disadvantages transpired. At that time, hospital refunding in Germany was based on the length of stay (in the hospital as well as in the ICU); furthermore, an ICU occupation rate of 95% was regarded as the target by administration. Consequently, the IMC beds were only used after all the ICU beds had been filled. Thus, the ICU/IMC beds were not always used appropriately. Furthermore, laboratory tests and x-rays (and possibly other tests) were presumably not used as restrictively as they should have been in intermediate care patients. Of course, treatment was adapted to the individual patient's need. So, the mixed model requires a very strict control of the level of monitoring and diagnostic measures. Such differentiation cannot be left at the discretion of an individual; it requires precisely defined standard operating procedures (SOPs).

Recently, a restructuring process for ICUs in large teaching hospitals in Germany has begun. As intensive care medicine in Germany has a multidisciplinary access, there were often several different, specialty-related ICUs in university hospitals, such as for surgery, cardiac surgery, neurosurgery, neurology, cardiology etc. For reasons of economy, standardization and quality, these will now be brought together in some hospitals, for example to a centre for surgical intensive care medicine, under the management of a full-time intensivist (often an anaesthesiologist). As a consequence, there is now a violent debate between the various specialties concerning the distribution of power and competence (Burchardi 2005).

In large university hospitals with more than 1000 beds, such centres for intensive care medicine become rather large, sometimes with up to 40 beds or more. With these dimensions a mixed model which also incorporates intermediate care patients, will not be realistic. In future such hospitals will require a great number of step down beds, which will need to be kept apart from the ICU. In my view, it will then be rational to run such IMC units completely separately with a different staff and management. It may also be a good idea, not necessarily for political reasons alone, to keep such step down units specialty-related and to let these specialties manage their own IMC units. This will allow these specialties the opportunity to retain influence, control over bed capacity, control and competence of patient care, and some teaching capacity.

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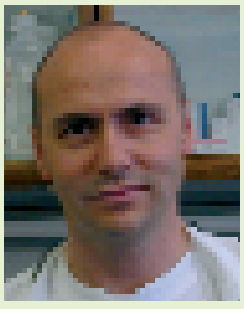
References are available on request: editorial@icu-management.org

An interview with **Prof. Marko Noc** on **management** in intensive care

As a teacher, researcher and manager in intensive care, Professor Noc promotes international training of his personnel, analyses treatment outcome continuously, promotes evidence based treatments and develops clinical pathways for the most common causes of admissions.

Table 1: A typical day

0715	Arrival
0715 - 0800	Check the regular and electronic mail
0800 - 0830	Situation in the department: patients, admissions, problems; brief morning round
0830 - 0945	Morning meeting for reports on patients and planning treatments. Present: physician team which was on call, and all daily team members including students, interns, residents
1000 - 1345	Various tasks including administration, interventional cardiology procedures, assisting with patient complications, consultations, research etc.
1345 - 1430	Afternoon meeting for reports on patients and special issues for the physician on call
1430 - 1600	Various tasks including administration, interventional cardiology procedures, assisting with patient complications, consultations, research etc.



INTERVIEWEE
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Introduction

Professor Marko Noc has worked in intensive care for 16 years and was appointed the Director of the Centre for Intensive Internal Medicine at the University Medical Centre of Ljubljana, Slovenia in 2001. This Medical Centre is by far the largest tertiary hospital in Slovenia, with around 2500 beds, 6400 employees and over 730 attending physicians. Professor Noc's specific area of expertise is cardiac care and in particular acute coronary syndrome, sudden cardiac death/cardiopulmonary resuscitation and interventional cardiology. With 8 attending physicians and 38 nurses, his department for Intensive Internal Medicine has 14 beds and a turnover of 1300 to 1350 patients per year. The nurse to patient ratio is 1 nurse to 1.7 patients during the mornings and slightly less afternoons and evenings. The intensive care mortality rate is 15-20%.

What are the main directives of your role?

I'm responsible for medical, research and education issues. I have very limited or no influence on budgeting, financial management or negotiation with insurance organizations. I would say that 70% of my time is devoted to clinical issues, 25% to personnel issues and only 5% to financial issues. I continue with routine clinical work, being on call for the intensive care unit, emergency department, interventional cardiology procedures for acute cardiac patients, and for interhospital helicopter transport of critically ill patients.
At a strategic level, I'm responsible for the development of clinical pathways for the most common causes of admission. We have developed pathways for acute coronary syndrome, massive pulmonary thromboses and guidelines for emergency bedside echocardiography. Our greatest success is probably a network for treatment of acute ST-elevation myocardial infarction with primary percutaneous coronary intervention (PCI) for the whole Ljubljana region (1.3 million people). I'm also involved with plans to develop more contemporary concepts and to design a new department of adult intensive care in our hospital.
Before I was appointed Director, I presented a plan of work targets against which my performance is now appraised. We continuously assess the quality of routine clinical work in our everyday meetings, and we participate actively in Slovenian and international scientific meetings and peer review publications.

How would a typical day proceed?

(See table 1) Attending physicians work from 0800 to 1600 hours. Our attending physicians also take regular calls for the emergency department and for the interhospital helicopter transport of critically ill patients. Interns and residents work in 3 shifts (7:00-14:00, 14:00-21:00 and 21:00-7:00) during the week and 2 shifts (8:00-21:00 and 21:00-8:00) during weekends and holidays. Nurses work in 3 shifts (7:00-14:00; 14:00-21:00; 21:00-7:00) during the week and 2 shifts (8:00-21:00 and 21:00-8:00) during weekends and holidays.

Give an example of two extremes in the types of tasks you have to fulfil

There's an enormous contrast between attending a meeting of directors from different departments of medicine and performing primary PCI in a patient with evolving ST elevation acute myocardial infarction. I don't have any problems with these extremes; it's just a matter of switching my approach as appropriate and it makes my professional life very dynamic and interesting.

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

Having to say "no" to a young, smart and enthusiastic physician, who wanted to become part of our ICU team, because I could not get a position for him.

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

We manage to bring many very sick ICU patients back to normal life, by implementing contemporary evidence based medicine. We have excellent facilities for management

of acute cardiac patients: 24-hour echocardiography (TTE-TEE), 24-hour interventional cardiology, extensive experience with intraaortic counterpulsation, mechanical ventilation and haemodynamic monitoring. Our results in treatment of acute cardiac patients and in particular of acute coronary syndromes are therefore very good. Our department is, however, significantly restrained by the architecture. We have two rooms for five patients, and two further rooms, each for two patients, and a continuous lack of free beds. Because we can't isolate patients appropriately, nosocomial infections represent a significant problem, which increases morbidity and mortality of chronic ICU patients. The main problem within the hospital is that there are too many separate adult medical intensive care units, for infectious disease, neurology and our department, and these should be centralized into two units, medical and acute cardiac ICU.

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

For management, I had no special training. I had the standard national medical and research training and extensive training in the US for almost four years. My department is supported by the complete university hospital with all its clinical departments. I have regular contact with heads responsible for medicine and staff. I also have medical contacts and support by e-mail and phone with my good friends and former colleagues in Europe and the US. To direct an intensive care department well, you need to have a general and critical overview of intensive medicine, and to stay involved in routine clinical work with the critically ill. It is important to continuously analyse the outcome of treatment and identify problems as early as possible. We need continuous outcome analysis, not only for the short term, but also for long term survival and quality of life in order to justify the hard work of intensive care personnel and the high financial costs of intensive care. We also need to use evidence based interventions rather than interventions which have no true scientific founding.

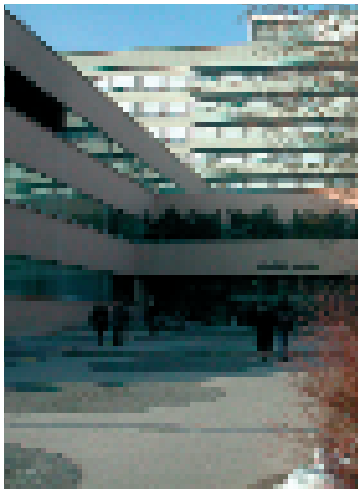
What sorts of medical/clinical management issues are you currently dealing with?

We're currently refining the system for primary PCI for ST elevation acute myocardial infarction for transfer-in patients (for regional non-PCI hospitals or directly from the field). We're also defining a protocol for management of patients after resuscitated cardiac arrest including indications for immediate coronary angiography/PCI and induced hypothermia. However, most of my time is currently occupied with clinical pathways for the most common causes of admission. For protocol development, we allocate different fields of adult intensive medicine to different attending physicians. Each is responsible to present one or more protocols regarding diagnosis/treatment. The protocol is discussed and approved at a meeting with all the attending physicians and I confirm the final protocol. I discuss the options for equipment at the meeting of attending physicians, and again I have the final decision to submit our selection to administration. At this level, however, a special committee comprising physicians and economists analyses the cost-effectiveness and selects what they consider to be the best option. True measures of cost-effectiveness are unfortunately practically non-existent in my hospital and in Slovenia in general.

What personnel issues are you dealing with?

I'm trying to get an additional position for an attending physician in our department For recruitment, I interview a candidate and analyse their education starting from medical school. Personality is very important, because one "troublemaker" can destroy the whole team. I expect candidates to attend additional education (fellowship) for one to two years in a leading institution in Europe or the US, and I ask them to do part of a rotation (internship, residency) in our department. This allows me the opportunity to gather my colleagues' opinions before making a final decision. To help retain staff, I try to select members carefully and maintain a good atmosphere in the department. I always take great care to acknowledge good performance. Conflicts are resolved immediately through discussion and I discuss negative issues only to avoid repeat occurrences in the future. I stimulate everyone for career development, helping with scientific writing, international contacts, and by arranging invited lectures at scientific meetings. I stimulate training in well recognized institutions around the world. I invite the attending physician and head nurse once or twice a year for a two day meeting in a pleasant environment, where we can discuss our work and also have some fun. We also have one or two annual events to bring all the department staff together.
Each attending physician has several fields of interest, for example education, research, sepsis, COPD exacerbations etc. As an intensive care team we are analogous to a government with several ministers advising, and me as the prime minister, needing to make the final decisions and carry the responsibility. I try to be fully open and supportive with my colleagues, and they know that my response is never "mission impossible." Since I became the director in 2001, only one of my eight attending physicians has left, and two of my six research/clinical fellows. Unfortunately, turnover is much higher amongst the nurses.

Thank you, Professor Noc, for this insight into the management of your department



Above: University Medical Centre, Ljubljana, Slovenia
Below: Professor Noc and his ICU team

General health care in Austria

Dr Alfons Hammerle gives an account of statistics profiling the general health care in Austria, and outlines recommendations for reform.

Socio-demographic factors

The population in Austria increased between 1991 and 2001 by 3%, to around 8 million, primarily due to an increase in the age groups over 45; the birth rate has declined continuously since 1991. By the year 2020 the population of Austria will have grown to 8.3 million, with a demographic profile of one out of five Austrians older than 64.

State of health

The most recent data show that life expectancy in Austria is 78.5 years for men and 81.2 years for women. The average death rate per year is 79,000 (36,000 for men, 43,000 for women). The most significant causes of mortality are cardio-vascular diseases and cancer. Regarding potential years of life lost (death under 65 years), men have lost significantly more years of life than women due to accidents, injuries and poisoning, whereas in women cancer predominates.

In contrast to the trend of decreasing mortality, the number of hospital admissions has risen to around 2.4 million. For men the most frequent causes of hospital stays are injuries and poisoning, whereas the leading indications for women are pregnancy-related.

The cancer incidence rate is about 38,000 new cases per year (18,500 men and 19,500 women). In men, the most frequently localised tumours are the prostate (3,700 cases), lungs (2,600), colon/rectum (1,500) and the urinary bladder (1,200). In women, breast cancer (4,500) is followed by colorectal cancer (1,600) and pulmonary cancer (1,100).

Absence from work due to illness is primarily caused by colds or upper respiratory infections (970,000 cases in 2001), orthopaedics, rheumatology (460,000) and intestinal infections (23, 500).

In 2002 around 348,000 persons (4.3%) received nursing benefits. Levels of need are rising with age and thus the demand for nursing care is growing: the relevant share is more than 50% among persons over 80 years. The majority, i.e. 3 out of 4 of the population, believe that their own state of health is very good or good, and the better educated a person is, the more satisfied they are with their state of health.

Factors influencing health

The share of overweight persons aged over 15 years (Body-Mass-Index BMI 26-30) has risen to 27.6% in men and 17.1% in women (total about 1.5 million people). 10.8% of men and 10.2% of women (total around 700,000 people) are massively overweight (BMI over 30). Approximately 8.3% of the Austrians over 15 years are suffering from arterial hypertension (530,000 people). Around 11% have total cholesterol levels of more than 200 mg/dl. According to experts more than 500,000 persons in Austria suffer from diabetes mellitus.

30% of the population are daily cigarette smokers (men 36%, women 27%). The share and number of female smokers, in particular young people, is rising. The number of chronic alcoholics is estimated to be around 330,000 (20% of them female).

Health promotion and prevention

The national expenditures for health promotion and preventive care are 85% covered by the social insurance funds (722M Euros). A further 66M Euros are sourced from the Federal Government. Additional contributions of 46M Euros are supplied by the provinces and 13.5M Euros by Local Governments.

Implemented measures of health care and preventive health care differ between the provinces.

Between 1997 and 2001, 569,000 women and 370,000 men on average underwent precautionary medical examinations (10.1% of men and 14.1% of women).

Health care institutions

Approximately 150 hospitals of the Provincial Hospital Funds and 7 accident hospitals of the Austrian Social Insurance for Occupational Risks provide for inpatient care of acute cases in Austria. Besides the Fund hospitals, health care services are offered by about 40 private hospitals. In the year 2000, Fund hospitals had a total number of 50,500 beds, an occupancy rate of 84% and treated 2.4 million inpatients with an average length of stay of 5.9 days. Inpatient staff comprises about 7,400 full-time equivalents (FTEs) of physicians and 39,300 FTEs of occupation groups.

Extramural medical care is covered by a total of approximately 16,400 established physicians

The Austrian Red Cross leads the ambulance services, which has 460 centres. Around 100 have cars or ambulances for emergency physician`s services. These centres pay for 4,000 staff and have about 30,000 voluntary workers and around 2,200 young men performing social military service. In the field of mobile nursing and social

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services, approximately 7,900 FTE skilled nurses and other skilled care staff, nursing assistants or assistants for elderly patients work throughout the whole of Austria.
Austria has approximately 1,200 public pharmacies, which equates to 1 public pharmacy for every 6800 inhabitants. Additionally pharmacy services are provided by 8,200 doctor`s pharmacies of established physicians.
In 2001, health expenditures in Austria amounted to approximately 16.4 billion Euros, or 7.7% of the gross domestic product. About 68% of this budget is accounted for by public health expenditures.

Conclusions

The following characteristics and trends are apparent in the Austrian Health Service:

- An uneven regional distribution of acute beds and hospitals;
- A continuously increasing number of hospital admissions, despite the gradual reduction in acute beds;
- An increase in the number of outpatient contacts;
- An uneven regional distribution of rehabilitation capacities;
- A rapidly expanding need for long-term care, and institutions dedicated for this purpose;
- Continuously increasing costs in the health and social sectors.

An integrative planning of the health care sector therefore seems advisable. According to Article 15a of the Federal Constitutional Act, this integrative planning should include all sectors of health care.

References are available on request: editorial@icu-management.org

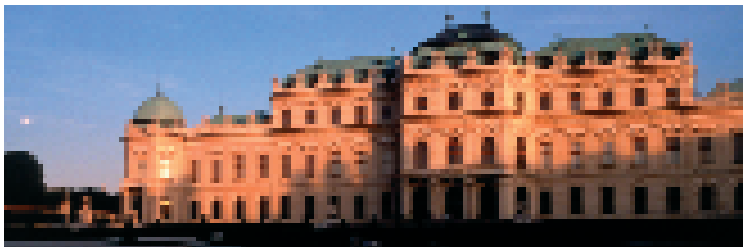
Austrian intensive care associations

Austrian society of anaesthesiology, resuscitation and intensive care medicine (OEGARI)

OEGARI is a non-profit organization to support and develop anaesthesiology, resuscitation, intensive medicine, pain therapy, emergency care and catastrophe medicine, with the objective of providing Austria with the best possible care in these fields.
Membership is open to doctors already specialised or in training for anaesthesiology. Applications require support from two ordinary members and are voted in by the general assembly. Austrian doctors or scientists from any specialty, who support the aims of the society may become extraordinary members, but cannot be elected on to the executive committee.

In addition to an annual congress, the society organizes:
- meetings, presentations and scientific gatherings;
- training courses in relevant topics of medicine for professionals other than doctors;
- resuscitation and emergency care courses for members of the public;
- co-ordination of professional education for doctors to help standardise medical practice in anaesthesiology in Austria.

The society additionally supports scientific research in all related medical fields and promotes good personal and professional relationships with equivalent associations abroad, through study trips and participation in congresses abroad.



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Austrian society of medical and general intensive care medicine (OEGIAIM)

The society supports research in the field of intensive care, education and post-graduate education for doctors in intensive medicine.
Ordinary members may be doctors in intensive care medicine; extraordinary members are doctors from other fields, who are interested in contributing to the society's aims. Members may be professional individuals or legal organizations.
The society holds an annual meeting, organizes training sessions and seminars, and has published "Intensiv-News" (free to members) for nine years. A further publication, "Intensivmedizin und notfallmedizin" is the official voice of the society and other German and Austrian associations active in the field of intensive and other medical specialties. Tables of contents and abstracts are available on line and full texts are supplied on subscription: http://link.springer.de/link/service/journals/00390/ tocs.htm

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Intensive care management in Austria

This article focuses on the current status of postoperative intensive care medicine in Austria, with special emphasis on ICU categorization and the requirements for board certification in intensive care medicine.

Overview

Currently (2003), the Austrian Federal Hospital Act reports a total number of 272 hospitals providing 67,708 beds for the Austrian population (8,117,754 inhabitants in 2003). About half of these hospitals are public institutions (133 hospitals). The total number of intensive care beds was 1,645 in 2003 (2.4% of all registered hospital beds) (Bundesanstalt Statistik Austria Hugelg 2003).

Intensive Care medicine in Austria is mainly performed by the following specialties: Anaesthesiology and Intensive Care Medicine (n=691, 36%), Internal medicine (n=584, 31%), Paediatrics (n=275, 14%), Surgery (n=175, 9%) and Neurology/Neurosurgery (n=116, 6%).

Classifications

According to the federal government (Modell 2004) all intensive care units in Austria are classified on the basis of structural criteria and level of care provided at three levels (I-III). This classification was created to meet the requirements of the performance-based billing system introduced in 1997. Level III indicates high-end intensive care medicine, caring for the most seriously ill patients requiring maximum effort (TISS-28 ≥32) and the highest nurse per bed ratio (≥3). Level I units treat patients with fewer personnel and less technical equipment (TISS-28 ≥22, nurse/bed ratio ≥2). Level II units are characterized by a mean TISS-28 ≥27 and a nurse/bed ratio of ≥2.5 (Metnitz et al. 2005). The minimum number of beds required for classification as an intensive care unit is six for all categories. These data are provided in part by the Austrian Centre for Documentation and Quality Assurance in Intensive Care Medicine (ASDI), which was approved by the Austrian federal government in 1997 (Metnitz et al. 1999). As mentioned, this definition has only been created for billing purposes, with each ICU receiving points for every patient treated per day.

For internal evaluation and continuing medical education purposes in postoperative ICUs, the Austrian Societies of anaesthesiology and postoperative intensive care medicine (OEGARI and OEGIAIM) created an evaluation program on anaesthesiology ICUs in Austria. This program was started in 1993 with a questionnaire being sent to all anaesthesiology ICUs in Austria. Data were evaluated and a second evaluation was performed in 1997. According to the results from this evaluation, anaesthesiology ICUs were grouped into three different categories, A, B or C. A level A unit must have eight beds, >1000 ventilation days, a nurse/bed ratio >3.5 and a physician present the entire day. Category B represents units with a minimum number of 6 beds, >500 ventilation days, a nurse/bed ratio of 2.6-3.4 and a physician present at least 80% of the day. Category C requires a minimum number of 4 beds, >200 ventilation days, a nurse/bed ratio of 2.1-2.5 and a doctor present at least half of the day. This categorization is used for education and training purposes: category A units may offer full training in the specialty anaesthesiology and intensive care medicine for 24 months, category B for 12 months and category C for 6 months only.

Training and education in intensive care medicine in Austria

Special competence in intensive care medicine can be acquired in two different ways in Austria. The first route is by completing training in the specialty anaesthesiology and intensive care medicine, which takes at least six years, of which at least two years must be spent exclusively in intensive care training. Furthermore, a theoretical postgraduate course with examination is mandatory for all participants. In 2003, 1,752 specialists in anaesthesiology and intensive care medicine were registered in Austria, with the majority (n=495) working in the capital Vienna.

A second route through which to become a specialist in intensive care medicine is provided for board-certified physicians of the following specialties: internal medicine, surgery, paediatrics, respiratory disease, neurosurgery, neurology, or psychiatry. To specialise in intensive care medicine, members of these specialties must work exclusively in an ICU for at least three years, and training and education must be performed under the supervision of specialists in anaesthesiology and intensive care medicine, or a base discipline plus intensive care medicine. Training and education is performed according to the guidelines of the Austrian chamber of physicians. Each specialty has a certain core-curriculum set up by the individual specialties, representing a catalogue of procedures and special knowledge to be learned and practiced by the trainee (e.g. skills in echocardiography).

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Everyday Triumphs

Today, we remembered clearly why we chose this profession. Some healthcare heroes operate; and like any other heroes, we sometimes forget the real reasons we chose the profession. The old assumptions about how to run a hospital system don't work anymore. More and more, our desire to provide top patient care falls at odds with financial realities. And a lot of "state-of-the-art" technology seemed to complicate a hectic workplace. So we made a vital change. We discovered more sophisticated technology that actually simplified our lives. We found a way to achieve clinical excellence and balance our budget. To accomplish more and stress less. We can now rely on customer service as much as our patients rely on us. So today, we had time to focus a little more on the patient. Because we have a system designed for us. It just makes sense.

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sense and simplicity

Euroanaesthesia: ESA annual scientific meeting; Vienna May 28-31, 2005

Dr Drummond previews the philosophy, methods, and content of the coming ESA meeting.

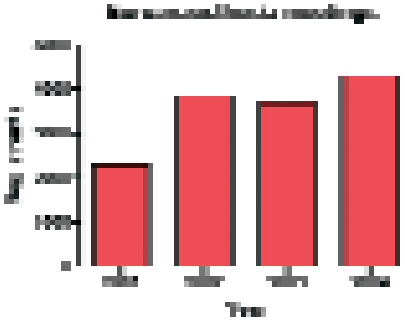

Figure 1: ESA annual meeting attendance

The European Society of Anaesthesiology is a young organisation, born in 1990. It has grown quickly, and a central feature of its success has been an attractive and popular annual Scientific Meeting, Euroanaesthesia. The winning formula has been maintaining a core expertise in the nuts and bolts of running a big scientific meeting, with a permanent Secretariat.

For programme content, we draw on advice and help from clinicians and researchers who are selected from the best of European anaesthesia. These successful annual meetings have grown over the years (figure 1). This growth is starting to limit the choice of centres where the meeting can be held, and a popular city is a vital ingredient for success. This year, the meeting will be held in Vienna, a location that we have used successfully before. The city is easy to reach, attractive, and has a great atmosphere. Coupled with the high reputation of the ESA scientific meeting, this promises to be a great success. In addition, this year represents the culmination of political fusion of all the European bodies associated with anaesthesia, to form a single organisation. The European Academy of Anaesthesiology, which confers a Diploma in Anaesthesiology, and the Confederation of European National Societies of Anaesthesiologists, have now amalgamated with the ESA. This organisation now speaks for anaesthesia with a single voice. The Vienna meeting will represent the first annual meeting of this new unified Society, although there has been a slow fusion over the last three years, with cooperation in the annual meetings.

Such a meeting should reflect the entire range of scientific progress and advancing knowledge in anaesthesia. The content has to be practical and address economic aspects as well as purely scientific themes. An important consideration is that many European anaesthetists also practise intensive care. Our on-site surveys show that certain subjects have an enduring popularity, particularly regional anaesthesia, and there are also important aspects of modern society such as the ageing population, increasing incidence of heart disease, and the increasing demand for evidence based and economic considerations. It's hard to single out specific highlights, since the intention is to have something for everyone. However, there is a large symposium planned on the uses of hypothermia, which is relevant to a number of special areas of anaesthesia, and where considerable development has been seen. It's prudent to plan most of the programme about a year in advance to allow arrangements with speakers, who are often in demand. However there may be "hot topics" that need addressing at shorter notice. This year, for example, we plan a symposium to address features of the sudden withdrawal of the COX-II inhibitor analgesics from the market. Other topics of current relevance are information technology and processing, and practical and organisational aspects of safety.

Features that are always popular include practical sessions with simulation, such as in airway management, and workshops where practitioners can discuss controversial topics and allow the audience to participate.

A conference like this is an important forum for the presentation of current research, using posters and small group presentations. After submission, which is entirely on-line, abstracts are judged by a panel of specialists, using carefully designed, norm-referenced criteria. Approximately 70% are accepted for presentation. The poster presentation process is designed to allow discussion and exchange of ideas between workers in the various fields, and can often be rewarding and encouraging, particularly for young researchers. Research is enriched and stimulated by such interchange. In addition, the ESA has set out to encourage first class research by selecting the best of the submissions for separate presentation and judging by a panel of experts, followed by prizes for the best three presentations.

I welcome you to come to Vienna in May and sample the variety and quality that the meeting will provide!

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Facing the challenge: **intensive care without walls** – ESICM annual congress

Drs Rhodes and Moreno preview the interaction, learning and dissemination of scientific knowledge offered by the ESICM's annual Congress in September.

This year the annual congress of the European Society of Intensive Care Medicine (ESICM) will take place at the RAI congress centre in Amsterdam from 25th to the 28th September. The motto and theme for this year's meeting is 'Facing the challenge: Intensive care without walls'. The meeting will be an exciting opportunity to catch up on research, science and educational matters relating to intensive care and emergency medicine.

The ESICM annual congress is a meeting developed and run by ESICM members for anyone with an interest in the critically ill patient, especially intensivists, anaesthesiologists, emergency physicians, internists and surgeons. The program for this year's meeting has involved many hundreds of ESICM members. The society has a number of sections each with a particular interest topic. Members of these sections propose ideas for the content and format of potential sessions. These are then further developed via section meetings and email discussion into formal proposals for specific sessions. The Congress Committee then incorporates these into the program that becomes the Congress, ensuring that all important topics are covered, that the aims of the meeting are fulfilled and there is no inequity in social, geographical or political content. This process ensures that each member of the society can influence the program and help direct the future of the congress. It also means that the congress is responsive to what the members (and other registrants) want and need.

An important part of running any congress is participation of relevant industries. These industrial partners support the meeting to a greater or lesser extent by being major sponsors of the society, participating in the industry exhibition, or simply by sponsoring one of the identified industry sessions. We see this partnership between the ESICM and industry as extremely important for the smooth running of the meeting. However, we also recognise that all science presented at the meeting, especially in the industry sessions, must be relevant and unbiased. The Congress Committee therefore oversees the content of all of these sessions and ensures that at least one non-industry sponsored expert chairs each session.

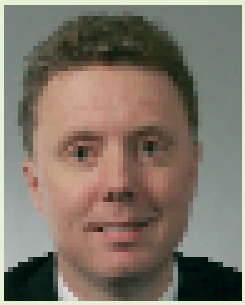
One of the main aims of the meeting is the advancement of cutting edge research related to Intensive Care. Much of the program is therefore available for researchers to present their work; over the last years we have consistently had over 1000 abstracts submitted! These are presented in oral or poster format, and are crucial to disseminate new research, for researchers to get peer review and debate their work, and also for young researchers to learn how to present. These sessions are therefore chaired and directed by senior researchers, who help their junior colleagues present, discuss and debate the work. We don't just encourage interaction; we make it happen.

Although research and science are extremely important, the Congress Committee has recognised that there are many trainees who attend the meeting, as well as more senior consultants who may need updating on basic practices. These groups need sessions with the emphasis on learning, rather than simply didactic thematic lectures. Throughout the congress there are several tracks devoted to this group of attendees. Intensive Care trainees are often working towards the European Diploma in Intensive Care, the syllabus of which is directed at least in part by the Society's PACT distance learning based program. These educational / continuous professional development (CPD) sessions are therefore advised on by educationalists as well as the educational / training committee of ESICM, and follow a number of formats. Post graduate courses prior to the congress include Fundamental Critical Care Support (FCCS) and Fundamentals of Major Disaster Management. Other courses include 'Intensive care without walls,' neurointensive care, non-invasive ventilation and septic shock. There are also CPD sessions within the congress itself, with the emphasis on interaction with the digivote system, competency based sessions, where experts describe the basic core competencies involved in the practice of Intensive Care and clinical challenges, where experts discuss every day clinical practice.

The annual congress of ESICM over recent years has gone from strength to strength. We feel that this increasing popularity is at least in part due to the involvement of such a wide number of our members in the development and running of the program. We hope and believe that the balance of the content is optimal with regards to science and education and that all major topics are covered.

We look forward to seeing you in Amsterdam

AUTHORS



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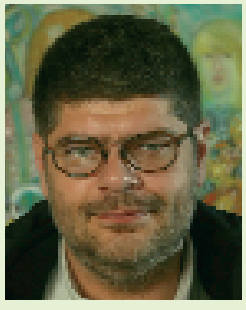
Cardiovascular Section
ESICM



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18th annual congress

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Amsterdam, Netherlands
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Facing the challenge: Intensive care without walls

For physicians, nurses and other allied healthcare professionals

Abstract submission deadline
15 April 2005

First announcement

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MAY 2005

26-28 IX National Congress on Intensive Care Medicine / International Symposium on Non-Invasive Ventilation
Vilamoura, Portugal
www.spci.org/index2.htm

28-31 Euroanaesthesia 2005 Annual Meeting of the European Society of Anaesthesiology
Vienna, Austria
www.optionsglobal.com/vienna/congress

JULY 2005

15-17 4th Summer Conference in Intensive Care
New York, USA
www.sccm.org/education/summer_conference/index.asp

AUGUST 2005

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

SEPTEMBER 2005

17-21 European Respiratory Society 15th Annual Congress
Copenhagen, Denmark
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

NOVEMBER 2005

10-12 2nd Congress of the European Federation of the Critical Care Nursing Association
Amsterdam, The Netherlands
www.efccna.org/congress2005.htm

JANUARY 2006

21-25 35th Critical Care Congress
New Orleans, Louisiana, USA
www.sccm.org/education/annual_congress/index.asp

FEBRUARY 2006

3-4 11th International Symposium on the Critically Ill Patient
Sevilla, Spain
www.infections-online.com

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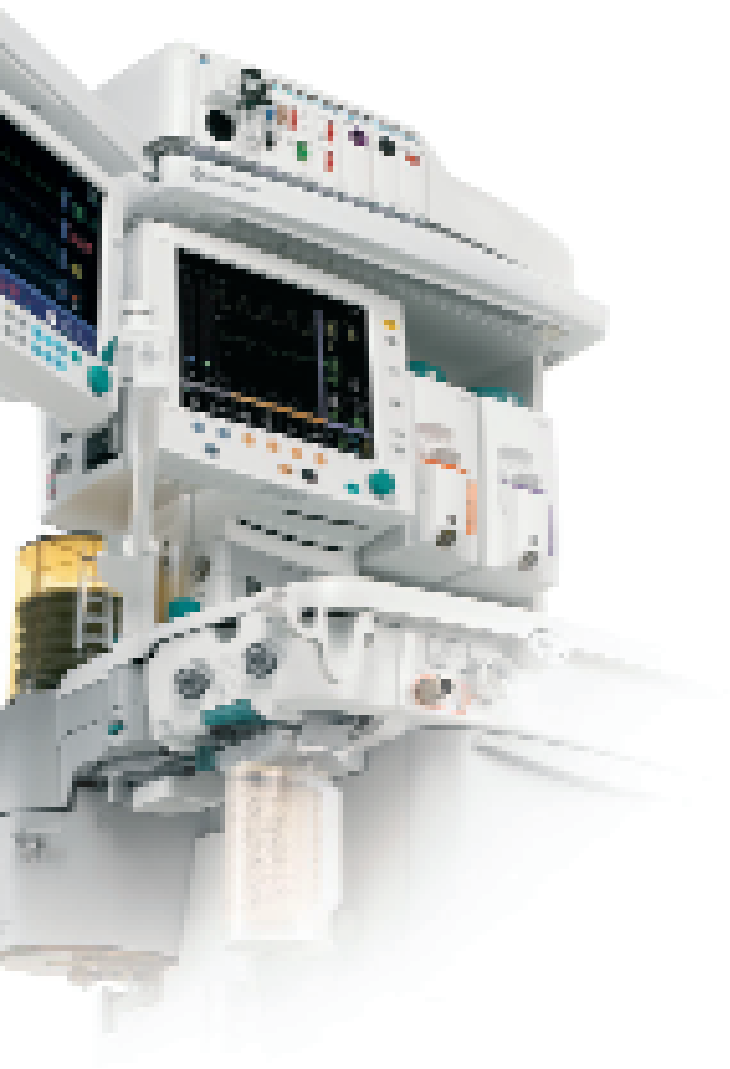

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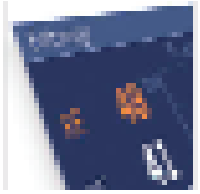

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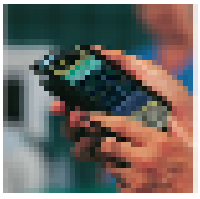

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