Journal of Clinical Monitoring and Computing (2006) 20: 117–144
DOI: 10.1007/s10877-005-9003-y

Abstracts

EUROPEAN SOCIETY FOR COMPUTING AND TECHNOLOGY IN ANAESTHESIA AND INTENSIVE CARE (ESCTAIC)

Aalborg (Denmark), September 7–10, 2005

Received: 14 November 2005, Accepted: 14 November 2005.

HOW TO GET PROCESS MANAGEMENT FLYING? FROM PROCESS MANAGEMENT REQUIREMENTS TOWARDS USE-ORIENTED TOOLS

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Process management furnishes a crucial issue for any business support. The question arises of how to support process management with maximal efficiacy and user acceptance by the same time. This presentation presents a use-oriented approach towards process management that is based on POWM (Process-Oriented Knowledge Management). POWM distinguishes itself with two regards. Firstly, an intuitive system approach allows for the capture of process know how by domain experts rather than relying on any third party consultant. Secondly, an individualising methodology supports the customisation of processes to individual constraints of the task at hand.

This presentation gives an overview of process management concepts and tools. Specific attention will be devoted to use-oriented aspects. Major process modelling and management concepts call for modelling experts, i.e. people trained for analysing processes and for employing appropriate modelling primitives of the underlying methodology and tool box. Once switching to a domain expert point of view, intuitive means for process capture, planning and execution gain importance in particular in a use-oriented stance.

POWM introduces the metaphor of processes as main interaction mean for organising work routing. Process activities, process planning and execution are organised in the context of this metaphor. Moreover, process-related documents are also managed according to this metaphor. In particular the latter improves the usability and acceptance of the approach significantly.

However, process patterns do not fit any bill. Hence, task-specific customisations are required. The question arises of how to capture and reuse know how about such customisations. POWM provides a methodology for the capture and reuse of task and project-specific constraints that impact process patterns. The process individualisation component of POWM allows one to specify task-specific constraints and related impacts on process patterns. The presentation will report on experiences gained in the engineering domain. Further experiences will be presented for the clinical domain with the AGIL shell that employs agent technology for the partial automation of certain process activities.

DO TRAIN DRIVERS DEFINE TIME TABLES? ENABLING WORKFLOWS IN ANAESTHESIA AND INTENSIVE CARE BY STRATEGIC INFORMATION MANAGEMENT FOR HOSPITALS AND REGIONAL HEALTH CARE

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Introduction: Conferences like ESCTAIC show that anaesthesists are quite offen dedicated to develop and introduce modern tools for supporting information processing workflows in anaesthesia and intensive care. Workflows (not only) in this disciplines are part of hospital wide or even regional wide workflows concernig patient care. Focussing only on anaesthesia and intensive care may face a serious loss of integration and quality of care.

Methods and Results: Since its information systems are constituent part of the respective hospital or the regional health care system, enterprise architecture planning is needed to construct integrated information systems [1]. The 3-layer-graph-based-meta-model ($3LGM^2$)[2] and the corresponding modelling tool ($3LGM^2$-tool)[3] supports this planning process by a means for modelling hospital's functions, supporting application systems, computers, and their relationships. A practical guideline for preparing strategic information management plans [4] guides through the planning process.

Conclusions: Using the methods proposed clearly shows interdependencies between workflows in anaesthesia and intensive care on the one hand and hospital or region wide workflows. Integration strategies and interfaces can be derived from this analysis. The need for a central information management and for strategic information management plans in hospitals becomes evident.

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WORKFLOW PROCESS SUPPORT FOR THE CLINICAL ROUTINE – A COMPARATIVE ASSESSMENT OF HOSPITAL INFORMATION SYSTEMS (HIS)

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Introduction: Growing medical possibilities and administrative requirements have increased the information and documentation work load within the hospital dramatically. The improvement potential by the implementation of an appropriate hospital information system (HIS) is obvious. But when it comes to the selection of an adequate software solution, not only the direct costs for purchasing, customizing and implementing such a system, but also its potential for improving clinical workflows and meeting user expectations have to be considered [1, 2]. In this context a systematic user assessment was used together with the German Heart Institute Berlin for getting a comparative overview about the functionality and general impression of different HIS alternatives.

Methods: Based on a typical patient career for the German Heart Institute Berlin altogether 18 process tasks were predefined, that should be supported by the implementation of a HIS: 1 patient admission/admission planning; 2 outpatient admission; 3 diagnostics (lab/X-ray); 4 result & billing documentation; 5 inpatient admission; 6 cardiac catheter & OR planning; 7 resources planning (OR theatre/staff/CT); 8 cardiac catheter documentation; 9 OR documentation; 10 nursing documentation; 11 medical documentation; 12 medication; 13 quality assurance; 14 coding; 15 patient discharge; 16 medical discharge summary; 17 medical controlling (DRG grouping); 18 billing. Based on this process flow different producers of HIS solutions were invited to present their product alternatives within 180 min to an interdisciplinary expert team from the German Heart Institute Berlin (3 physicians, 3 nurses, 3 IT specialists and 2 administrators). Then the functionality of the software alternatives was assessed for each of the 18 predefined work tasks individually by each team member between "very good" (1 pt), "good" (2 pts), "satisfactory" (3 pts), "fair" (4 pts) and "poor" (5 pts) or "no statement possible". In addition to that the general impression of each HIS was assessed using the same scale and 8 additional categories: 1 functionality; 2 adaptability; 3 organizational & process support; 4 routine support; 5 ergonomic design; 6 homogeneity; 7 safety for the future; 8 overall impression.

Results: Using this study design for 7 different software solutions (Orbis from GWI, ISHmed from TSI, Soarian from Siemens, iMedOne from ITB, Phoenix from Parametrix, Lorenzo from Isoft and MedFolio from Nexus) significant differences within the average assessment of each systems' functionality based on the 18 predefined process tasks were found. As an example the average functionality assessment of the process task "15 patient discharge" varied for the 7 tested systems between "very good–good" (1.5 pts) and "poor" (5 pts). Also within the assessment of the 8 additional categories concerning the general impression significant differences were characteristic for the 7 HIS solutions. Nevertheless no HIS solution showed to be dominant within all 18 work tasks and the 8 additional assessment categories. Instead the calculation of each system's average functionality for the 18 work tasks and 8 additional categories showed that only two systems reached an overall result close to "good", while four systems were assessed "good–satisfactory" and one system was assessed as "satisfactory–fair" with altogether 6 out of 18 process tasks being assessed as "poor" by all voting experts.

Conclusion: The used assessment of the different HIS solutions based on the 18 predefined process tasks proved to be a very helpful basis for the selection of 3 software alternatives worth further investigation. But the selection of those 3 HIS alternatives could not be based on the numerical assessment results only. Instead also additional background information (about interface possibilities to other software solutions, the producers' developing and service strategies etc.) and hospital specific requirements (e.g. software solutions used by cooperating healthcare institutions, the importance of different process tasks being support etc.) had to be considered as well.

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SMARTCARE™ – OPTIMIZING WORKFLOW PROCESSES IN CRITICAL CARE THROUGH AUTOMATION

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Introduction: Improving the quality and efficiency of health care delivery are important objectives in critical care. Process engineering approaches to identify, organize and standardize health care workflows have been employed to meet these goals. Evidence-based clinical guidelines (CGs) for critical care are among these approaches. Their impact on outcome measures have been investigated and quantified in several clinical studies, e.g. [1]. Outcome measures that were studied include the reduction of hospital stay, mortality, human errors, medical device induced complications and workload of clinical staff. A logical next step is now the implementation of standardized health care processes into medical technology by allowing CGs to be executed by medical devices. This could provide automated standardized workflow process support. Dräger Medical's SmartCare™ technology is a platform that allows the implementation and automatic execution of various CGs within a wide range of medical devices. The SmartCare™ expert system comprises a universal engine and a set of executable knowledge bases that each reflects a certain critical care process, as described by a CG. An expert system construction suite (Solvatio, iisy AG, Rimpar, Germany) is used to facilitate efficient, visual-oriented knowledge modeling as well as the transition to the runtime environment. It seamlessly combines process-, knowledge- and software-engineering tasks. The core paradigm is that if a medical device allows for *reading* access to its measurements, settings, and contextual information as well as for *writing* access to its settings, then every clinical guideline for that medical device is potentially automatable [2].

Currently the automation of a specific process for weaning patients from mechanical ventilation has been implemented in a commercial product. SmartCare™/PS as an add-on for EvitaXL (Dräger Medical, Germany) provides automated control in pressure support ventilation. It implements a weaning CG clinically developed by Dojat and Brochard [3].

Methods: A multi-center, randomized controlled study was carried out in five university hospitals. 144 medico-surgical ICU patients were enrolled in this study. Approximately half of the patients ($n = 70$) were randomized to be weaned following the conventional weaning protocol used in the respective hospital, the other half were weaned using the automated SmartCare™ approach ($n = 74$).

Results: In comparison with manual implementation of conventional weaning CGs used in these intensive care units, SmartCare™/PS reduced weaning duration by 50%, total duration of mechanical ventilation by more than 30% and the ICU length of stay by almost 30% [4].

Conclusion: The automated execution of CGs by medical devices is a logical and beneficial progression of workflow support in health care. The implementation of additional CGs is expected to demonstrate the efficiency of SmartCare™ technology throughout the complex development process from knowledge acquisition to knowledge execution.

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VENTILATION INHOMOGENEITY–MODELLING AND ANALYSIS OF INERT GAS WASHOUT CURVES

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There is a new interest in lung volume measurements during mechanical ventilation since some ventilator manufacturers have recently incorporated this feature in the ventilators. Lung volume measurement with this approach is based on nitrogen washin/washout using fast oxygen and carbon dioxide analyzers and assuming that the nitrogen concentration is equal to 100 percent minus the sum of oxygen- and carbon dioxide concentrations. By plotting the tracer gas concentration, i.e., nitrogen, against the accumulation of tidal volumes washin/washout curves can be constructed and the mixing of alveolar gas, i.e. ventilation inhomogeniety, can be estimated. Knowledge of alveolar gas mixing may be used for diagnosing underlying lung conditions, i.e., obstructive lung disease, as well as for optimizing the ventilator therapy. Many different indices for assessing alveolar gas mixing have been proposed, but none have been widely used during mechanical ventilation, mainly due to lack of easy and accurate methods for tracer gas washin/washout during ventilator treatment [1]. The indices existing can be divided in compensated and non-compensated for changes in tidal volumes, dead space and lung volume. Theoretically, the compensated ones should more accurately evaluate the inherent property of the lung function and the changes in gas mixing produced by changes in ventilator settings. However, the different indices, including the compensated ones, are more or less sensitive to the tail of the washout-curve. The indices, which are more sensitive, e.g., pulmonary clearance delay, give very high values in patient with obstructive lung disease, under the condition that washout is continued for a prolonged period [1, 2]. Based on theoretical considerations and calculations as well on patient studies, we have proposed that the compensated indices; multiple breath alveolar mixing and pulmonary clearance delay have the best properties to be used during mechanical ventilation [1–3].

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THE VALUE OF REAL TIME PHARMACOKINETIC AND PHARMACODYNAMIC MODELING IN CLINICAL CARE

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A real-time pharmacologic display showing the drug administration history, predicted drug levels, drug interactions, and drug effects could enhance the safety of anesthesia. In the intensive care unit, sedatives and analgesics could be managed more effectively to control agitation and pain.

We have developed a drug display which helps the clinician visualize the pharmacology of the drugs given to the patient. Pharmacokinetic models predict past, present, and future drug concentrations and pharmacodynamic models estimate drug effects on the patient's state of sedation, analgesia, and neuromuscular blockade. The models translated drug doses into drug concentrations and drug effects.

We studied 24 patients who received propofol, remifentanil, and fentanyl during abdominal laparoscopic surgery. We recorded times for loss of responsiveness, tracheal intubation, skin incision, and return of consciousness. We used the pharmacokinetic models to calculate the opioid and propofol effect site concentrations at the time each event occurred. At the end of the case, our sedation response surface model quite accurately predicted return of responsiveness. The tetanic and algometry models also adequately predict the responses observed in the operating room.

A second study was conducted in a high-fidelity anesthesia simulator with 24 anesthesiologists. One-half of the subjects used the drug display. Subjects induced anesthesia, intubated the patient's trachea, cared for the simulated patient throughout a simulated shoulder surgery, and then awoke and extubated the patient following skin closure. Subjects who used the display managed drug delivery more effectively by keeping heart rate and blood pressure closer to normal, reducing the rise in heart rate and blood pressure associated with painful surgical manipulations and the fall in heart rate and blood pressure associated with drug overdose. The simulated patients woke-up faster (4.5 ± 3.3

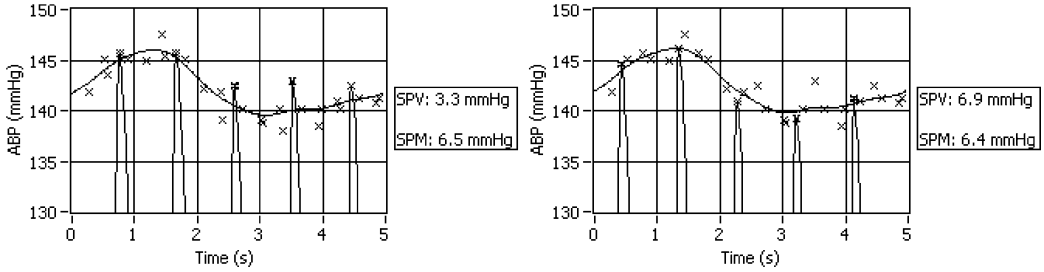

Fig. 1. Subsequent systolic modulation signals (time window of 30 seconds).

versus 7.5 ± 2.1 minutes) without hemodynamic complications. Participants who used the display reported a decrease in mental demand, effort, and frustration, and an increase in perceived performance.

Pharmacologic modeling has been successfully incorporated into a display that supports drug management in the operating room. Preliminary clinical studies indicate that the models adequately predict the clinical effects of intravenous anesthetics. A real time presentation of drug pharmacology can result in better patient outcome.

SYSTOLIC PRESSURE MODULATION

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Introduction: Systolic Pressure Variation (SPV) is defined as the difference between maximum and minimum systolic pressures during one cycle of ventilated breathing. The SPV increases for decreasing (circulating) blood volume and can therefore be used to detect hypovolaemia. Since the heart beats (semi-)independently, SPV values for subsequent respiratory cycles fluctuate highly, making it difficult to correctly detect hypovolaemia. We propose the notion of Systolic Pressure Modulation (SPM), which is more consistent over time. Fujita et al. mentioned a similar method, but neither a derivation nor a justification of the method was given [1].

Methods: The heart rate is in general not an integer multiple of the respiratory frequency. Therefore, systolic peaks for subsequent respiratory cycles have different alignments with respect to the inspiratory start. This implies that causes that give rise to the variation of systolic pressures [2] have differing influence on the systolic peaks for subsequent respiratory cycles. The effect results in a modulated pressure signal. Systolic pressure peaks then represent samples of the modulation envelope of this signal. The SPM is defined as the difference between the maximum and the minimum values of the envelope. Fluctuations in subsequent SPV values are caused by the fact that the points used for calculation alter each cycle.

Results: Figure 1 shows two subsequent systolic pressure modulation signals, using a time window of 30 seconds. Although the SPM does not change much, the SPV values differ a lot.

Conclusions: We propose a new method that does not show the fluctuations that occur in subsequent SPV values and results in a more consistent indicator for hypovolaemia.

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COMPUTER CONTROLLED ESTIMATION OF NONLINEAR RESPIRATORY MECHANICS USING CLINICALLY AVAILABLE MEASUREMENTS

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Introduction: In clinical practice linear models used to describe respiratory mechanics are often a poor description of pathophysiological processes. To overcome these limitations, this abstract presents a nonlinear respiratory mechanic model, whose parameters can only be identified from complex respiratory patterns. A computer controlled experiment is proposed to identify this model, using only measurements and equipments routinely available in the ICU.

Methods and results: The model of respiratory mechanics (Figure 1), modified from Barbini et al. [1], uses a sigmoid function to describe the nonlinear pressure-volume relationship of both collapsible airways (V_c) and alveolar space (V_a). Airways are modeled as three nonlinear resistances representing upper (R_u), central (R_c), and lower (R_l) airways.

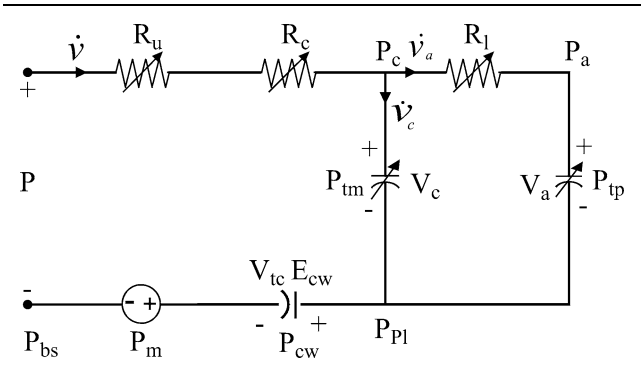

Fig. 1. A nonlinear model of respiratory mechanics.

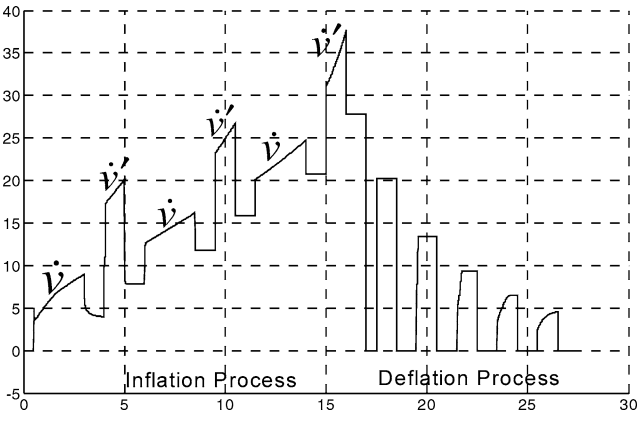

Fig. 2. A simulated pressure-time plot illustrating the data necessary to indentify the model.

This model has 11 parameters which, assuming a constant chest wall compliance, can be identified from the experiment illustrated in Figure 2. A Servo 300 ventilator (Maquet) is computer controlled to deliver inspirations at different constant flows ($\dot{v}$, $\dot{v}'$) with airway occlusions in a long inflation process, and immediately followed by a long passive deflation process consisting of expirations interspersed by occlusions. From pressures and flows measured at the mouth, varying both flow and pressure enables identification of flow, volume and pressure dependant resistances, and placing occlusions at different volumes allows identifying static pressure-volume curves.

Conclusions: This abstract has presented a computer controlled experiment to identify the nonlinear properties of respiratory mechanics, using only measurements and equipments routinely available in the ICU. Fitting such a complex model may provide a tool for understanding respiratory mechanics and optimizing ventilator settings in the ICU.

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SIMULATION MODEL OF BLOOD O_2 AND CO_2 CONTENT AND BLOOD ACID-BASE CHEMISTRY

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Introduction: *Siggaard-Andersen (1960, 1962)* constructed the pH-log(pCO_2) titration nomogram with Buffer base and Base excess (BB & BE) curves. Present automats used for clinical measurements work at temperature of 37°C but still commonly use the original non-corrected equations derived at 38°C. Moreover, the evaluation of the acid-base status changes which follow the plasma protein concentration disturbances is still very problematic because normal plasma protein concentrations were assumed during the nomogram construction. The next approach is the "modern" description according to *Stewart's* strong ion difference *(1983)*. Unfortunately, due to a necessity of covering of entire pathways of sodium, potassium and chlorides, this approach is not very suitable for mathematical modelling of the acid-base chemistry (ABC). *Rees and Andreassen (2005)* have recently proposed a mathematical model of the blood ABC, considering the total O_2 and CO_2 components and the reactions in the plasma and erythrocyte fractions. Their model shows the links between the Stewart's concept of strong ion difference and the more traditional formalism of Siggaard Andersen's total buffer base.

Methods: Authors base their models on a set of independent "state variables". This set unambiguously determines the acid-base status and the O_2, CO_2 content of an isolated blood sample. The set is stated as follows: Temperature (temp), blood haemoglobin concentration (Hb), plasma albumin concentration (Alb), total blood O_2 content (O_2tot), total blood CO_2 content (CO_2tot) and so called Base Excess standard concentration (BEst). We define the BEst as the BE obtained under following conditions: temperature is virtually set at 37 °C, oxyhaemoglobin saturation is virtually set to be 100% and the level of plasma proteins is virtually set to be normal. In accordance with this definition, the actual value of BE equals to BEst corrected to respect the actual O_2tot, saturation, temperature and plasma protein content of the given sample. The BEst value is independent of the changes in CO_2tot, O_2tot, temp, Hb or Alb! Therefore, the BEst is only function of flows in H^+/OH^- and HCO_3^-. Other commonly measured variables, such as pH, pO_2, HCO_3^- content, oxyhaemoglobin saturation, etc. are fully dependent on the state variables and authors call them the "derived variables".

Results: The model of the blood acid-base and blood gases chemistry has been used as a subsystem in larger models. It has also formed a base for various clinical calculations (i.e. evaluation of the rebreathing examinations etc.)., The conversion of the state variables to the required derived variables and vice versa is crucial in such clinical applications. The model and its applications are available at http://patf-biokyb.lf1.cuni.cz.

Conclusions: The models are very important as a core of educational simulators while also being a very useful tool for non-trivial clinical calculations of physiological values. However, we are still fighting with a lack of consistent groundwork experimental data. The model was fitted on partial experimental data from various authors, but presently available data possess many imperfections (most commonly they don't cover areas of abnormal temperatures, abnormal concentrations of plasmatic proteins and low haemoglobin saturation). Hence, the team of authors design a fully automated experimental apparatus for the measurement of the acid-base and blood gases status of a blood sample under various conditions. It will enable us to obtain a unique consistent and comprehensive set of data, covering the areas of abnormal physiological values, for they commonly occur in critical care.

PULSE OXIMETRY–ITS IDEA, THEORY AND FUTURE

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It had long been a challenging problem to measure SaO_2 noninvasively and continuously. J. R. Squire solved the problem of how to measure both of incident light and transmitted light of the blood in the tissue. Using his idea E. H. Wood developed the first SaO_2 monitor [1]. But his system had shortcomings for clinical use. For instance, in a long term monitoring, unintentional shifts in probe position cause to tell us false SaO_2 value.

In December 1972, I noticed that the pulsation of tissue transmitted light reflects SaO_2 value. This idea of pulse oximetry solved the shortcomings. We made up a pilot model and gave a presentation on it in 1974 [2]. It is my great pleasure that pulse oximetry is now considered indispensable in modern medicine. On the other hand, many new problems with performance of pulse oximetry have emerged. We believed only a multi-wavelength system can solve those problems. We constructed the theory of pulse oximetry and realized the multi-wavelength system. The system proved to solve many problems with pulse oximetry.

The pulse oximetry uses pulsation of transmitted light Li and obtains Φij corresponding to SaO_2.

$$dAi = \log[(Li + dLi)/Li], \quad \Phi ij = dAi/dAj.$$

We noticed the theory of A. Schuster [3] can be used as the basis for theory of pulse oximetry. We noticed that the pulsation of tissue transmitted light is composed of arterial blood (a), venous blood (v), and pure tissue (t).

$$dAa = \sqrt{\underline{Ea(Ea + F)}} * Hb * dDa,$$
$$dAv_s = \sqrt{\underline{Ev(Ev + F)}} * Hb * dDv, \; dAt = Zt * dDt.$$

Where Ea = SaEo+(1−Sa)Er and Ev = SvEo+(1−Sv)Er. S is oxygen saturation. Eo and Er are extinction coefficient of oxy- and deoxy-hemoglobin, respectively. Hb is hemoglobin concentration. dD is pulsating thickness.

$$\Phi ij = dAi/dAj = (\sqrt{\underline{Eai(Eai + F)}} + \sqrt{\underline{Evi(Evi + F)}} * V + Exi)/(\sqrt{\underline{Eaj(Eaj + F)}} + \sqrt{\underline{Evj(Evj + F)}} * V + Exj).$$

Where V = dDv/dDa, and Exi = Zti*dDt/(Hb*dDa). An approximation of Exi was applied: Exi = AiEx2+Bi. Where Ai and Bi were experimentally obtained.

When approximated that the tissue is only error factor, unknowns are Sa and Ex2. Three wavelengths 805nm, 875nm and 660nm were used. $\Phi 12 = dA1/dA2$ and $\Phi 32 = dA3/dA2$ were obtained and Sa was calculated as a solution of simultaneous equations. The correlation between SaO2 and SpO2 was improved with this system.

When venous blood also is considered, unknowns are Sa, Sv, V and Ex2. Five wavelengths 805 nm, 875 nm, 660 nm, 700 nm and 730 nm were used. $\Phi 12 = dA1/dA2$, $\Phi 32 = dA3/dA2$, $\Phi 42 = dA4/dA2$ and $\Phi 52 = dA5/dA2$ were obtained and Sa was calculated. The motion artifact was eliminated without delay and flattening.

The 3rd error factor is the optics. Incident light scattering in the tissue causes light path differences depending on wavelength. To eliminate this error factor, a thin scattering plate on the incident side is necessary. To realize this idea, it is desirable to use a higher power LEDs.

The near-future pulse oximetry will show us its true nature of high-fidelity in measurement of SaO_2. It will play an increasingly important role in wide range of clinical phases.

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OPTICAL SENSING OF MITOCHONDRIAL NADH AND MICROCIRCULATORY FUNCTION IN CRITICAL CARE MEDICINE

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Introduction: Intact mitochondrial function was identified as a critical factor in normal tissue activity. However, monitoring and evaluation of tissue cellular bioenergetics and microcirculatory function have not yet been integrated into monitoring systems of operating rooms and ICUs. Therefore we developed a unique biomedical device that provides real-time information on mitochondrial NADH redox state as well as microcirculatory blood flow and hemoglobin oxygenation. The mitochondrial redox state is measured by the fluorescence of NADH, microcirculatory blood flow by laser Doppler flowmetry and Hb oxygenation by the two wavelength reflectometry approach [1, 2]. We hypothesized that during the development of cellular hypoxia blood flow redistribution mechanisms will protect the most vital organs (brain and heart) by increasing blood flow, while the less vital organs (GI tract, skin or urogenital system) will become hypoperfused and O_2 delivery will diminish. As a result of this mechanism the less vital organs will be the initial responders to O_2 imbalance and the last to recover after successful resuscitation..

Methods: In order to evaluate the viability of a less-vital organ we developed a three way Foley catheter that contains a fiberoptic probe in order to illuminate the internal side of the urethral wall. In order to perform small animal studies we developed a special probe inserted in a 3mm diameter PVC tube that was located in the small intestine. In few experiments we compared the responses of the brain to that of the intestine by IV injection of adrenaline. All data are collected and analyzed by a specifically developed software.

Results: In experimental animals (rats) a clear difference between brain and small intestine was found after sympathetic stimulation. In the brain a large increase in blood flow was recorded concomitantly with oxidation of NADH while a clear hypoperfusion and increase in NADH was found in the gut. The same difference between the brain and other less-vital organs (liver, kidney) under adrenaline injection was found as well [3]. Preliminary large animal (pigs) studies and clinical studies suggest that our monitoring approach is practical in collecting data from the urethral wall.

Conclusions: Monitoring of mitochondrial NADH in combination with microcirculatory blood flow and Hb saturation may shed new light on body O_2 balance and the development of occult hypoperfusion state. In the near future we will conduct clinical testing of the device in critically ill patients.

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BIOSENSORS AND NANOTECHNOLOGY: USING LIGHT TO GLUE BIOMOLECULES ONTO SENSOR SURFACES

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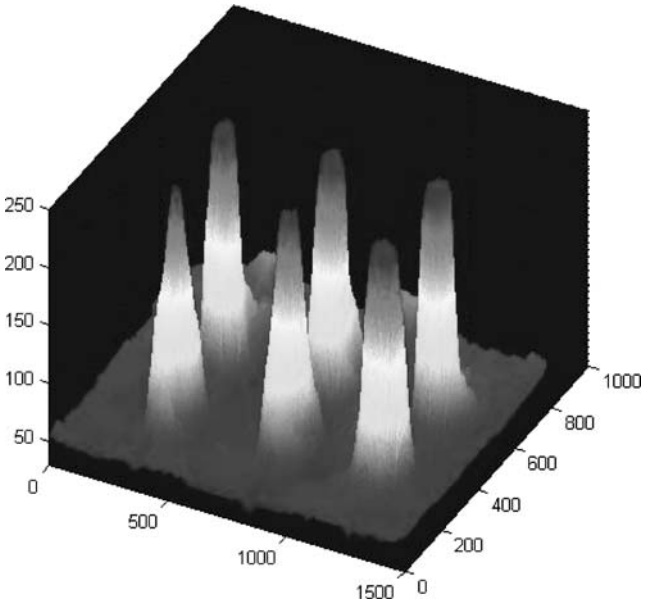

Biosensors development is expected to accelerate in a highly significant manner in the years to come. Sensors progressively become smaller, cheaper and often more sensitive. Multi-potent biosensors detecting a range of relevant human diseases from a single droplet of biofluid is likely to become a reality within the next decade. In this process enabling technologies are of tremendous importance. The presentation will focus on one such enabling technology: Micrometer resolved light induced immobilisation of proteins onto sensor surfaces. We have succefully developed a unique method for immobilizing proteins such as antibodies onto chemically activated glass, quartz or silicium surfaces with a precision that are expected to reach the 1 micrometer level. Prototypes for automated tools are being created at the moment allowing for multipotent sensor construction.

DURATION AND EXTENT OF THE DECLINE IN S_pO_2 AFTER BOLUS INJECTION OF INDOCYANINE GREEN

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Fourth-generation pulse oximeters display erroneously low oxygen saturation readings after IV administration of indocyanine green (ICG). This phenomenon is assumingly restricted to higher plasma levels of ICG and does not reduce the utility of pulse oximetry in intensive care and anesthesia.

Introduction: With regard to very few former studies [1] and case reports addressing artifactual low readings of functional oxygen saturation (SpO_2) after injection of indocyanine green (ICG) and other medical dyes, this study was designed to specifically evaluate duration and extent of the spurious decrease in SpO_2 of four newest-generation pulse oximeters after injection of ICG. ICG represents a tricarbocyanine type of dye with infrared absorbing properties, a peak absorption at about 800 nm near the isosbestic point, and is used as a diagnostic aid for blood volume determination, cardiac output, and hepatic function.

Material and Methods: After institutional approval and informed consent, SpO_2 and pulse rate (PR) of 10 ICU patients (aged 51–80 yrs) receiving 0.25 mg/kg ICG IV to evaluate hepatic function (comprising plasma disappearance rate, retention rate, and blood clearance of ICG) were additionally monitored by means of four fourth-generation pulse oximeters (Philips IntelliVue M3001, Masimo Radical, Dolphin Medical 2100, Nellcor N-595) via four randomly placed sensors (digit II-V). Minimum SpO_2 (t_2) as well as the beginning (t_1) and the end (t_3) of the decline of SpO_2 were marked offline and $\triangle t_1 = t_2 - t_1$, $\triangle t_2 = t_3 - t_2$ and $\triangle SpO_2 = SpO_2(t_1)\text{-}SpO_2(t_2)$ were calculated. Additionally, arterial blood samples were taken from an arterial line for co-oximetry to determine pO_2 (Radiometer ABL7xx series) at t_1, t_2, and t_3.

Results: Newest-generation pulse oximeters present with a slight and brief spurious decrease in SpO_2 after IV injection of ICG whereas co-oximetry and pO_2 remain unchanged. Notably, Student's *t* testing yields no significant statistical differences of $\triangle t_1$, $\triangle t_2$ and $\triangle SpO_2$ with all pulse oximeters ($p < 0.01$), however, the transient decrease in SpO_2 was significant ($p < 0.05$).

Conclusion: As ICG holds different molar extinction coefficients for different concentrations which additionally vary if proteins (e.g. albumin) are present, the effective absorption does not linearly increase with higher concentrations, but the primary absorption peak is shifted to the red thereby inducing an erroneous decrease in pulse oximetry readings especially at higher ICG plasma levels.

Table 1. Presents the results (mean±SD)

	Philips IntelliVue	Masimo Radical	Dolphin Medical	Nellcor N-595
$\triangle t1$ (s)	8.0 ± 1.7	6.5 ± 3.3	6.6 ± 2.3	5.4 ± 1.9
$\triangle t2$ (s)	4.6 ± 1.7	5.0 ± 1.8	6.6 ± 4.5	6.6 ± 3.1
$\triangle SpO_2$ (%)	5.7 ± 1.6	8.3 ± 3.3	5.3 ± 2.5	6.3 ± 3.0

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DETECTION OF FLUORESCENCE IN BLOOD USING FIBRE-OPTIC CATHETER

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Usage of photo-technology is limited in anaesthesia and intensive care field. Although an intravenous fibre-optic catheter has been clinically available, it is not utilised except for estimating oxy-haemoglobin fraction using absorbance spectrometry. Some molecules emit specific wavelength light, the fluorescence, when they are excited by light of higher energy or shorter wavelength. As the wavelength of the fluorescence is molecular specific and is different from that of incident light, fluorescence spectrometry has several advantages comparing with absorbance spectrometry. The purpose of this study was to develop techniques to detect fluorescence in blood.

Methods:

1. *Optical instrument*. The optical instrument was designed for the Abbott fibre-optic catheters to detect fluorescence of indocyanin green(ICG) in blood. The light source, a Xenon short arc lamp (HAMAMATSU Co, Japan) provides stable broadband light from 220 to 2000 nm. The light band is focused on 766 nm band pass filter. The filtered light is guided to a coupler that is specially designed for the optic module of the Abbott catheters and excites ICG. The coupler also receives the light emitted by blood and passed through the catheter. The 830 nm band pass filter is placed on just after the coupler to select the fluorescence emitted by ICG. The intensity of the fluorescence is measured by a photodiode (S-6024, HAMAMATSU Co. Japan) and an amplifier (C-5460, HAMAMATSU Co. Japan).

2. *In vitro study*. We investigated influence of red blood cell count or haemoglobin concentration on the fluorescence intensity. Human blood was diluted by saline and adjusted to three haemoglobin concentrations, 15, 10 and 5 g/dl. Relationship between ICG concentration and the fluorescence intensity was studied in the three blood samples in a tube. The concentration of ICG was gradually increased up to 3 μg/ml.
3. *In vivo* study. Three New Zealand White rabbits, 3.2–4.5 kg weight, were anaesthetised with ketamine and diazepam, and breathed spontaneously. A 5.5 Fr Abbott fibre-optic catheter was inserted from right jugular vein. The tip of catheter was placed at three positions; superior vena cava, right atrium and inferior vena cava under X-ray fluoroscopy, and recorded 830 nm signal output at each position. At the position of the minimum noise 5 mg of ICG was injected in the right jugular vein.

Results: The in vitro study showed that the relationship between ICG concentration and the fluorescence intensity was linear up to 3 μg/ml, and this relationship was almost same in the three blood samples of different haemoglobin concentrations. The in vivo study showed that the signal noise was minimum when the catheter tip was at the inferior vena cava all three rabbits. The 5 mg of ICG injected intravenously provided sufficient intensity of 830 nm fluorescence signal.

Discussion: This is the first report that fluorescence in blood was detected with a clinical available fibre-optic catheter. This fluorescence spectrometry with fibre-optic catheter is expected to show advantages in several clinical settings. This technique may improve the accuracy of cardiac output estimation because thermodilution method potentially overestimates the value resulting from heat shift to surrounded tissue especially in low cardiac output state. Although non-invasive pulse dye densitometry (PDD) is clinically available and provides blood volume and ICG elimination constant, the PDD does not work well unless peripheral arterial pulsation is sufficient. This technique possibly overcomes the weak point of the PDD and provides accurate values even in low blood circulation state. The fluorescence spectrometry is able to detect other intra-blood materials besides ICG, and has a possibility to be applied to various techniques.

Conclusions: We could detect the fluorescence of ICG in blood using a clinical fibre-optic catheter. The intensity of the fluorescence was independent of haemoglobin concentration.

SIMULTANEOUS ANALYSIS OF CLINICAL ENDPOINTS AND SIGNAL-TO-NOISE RATIO IDENTIFIES SUITABLE EEG PARAMETERS FOR MONITORING ANAESTHESIA

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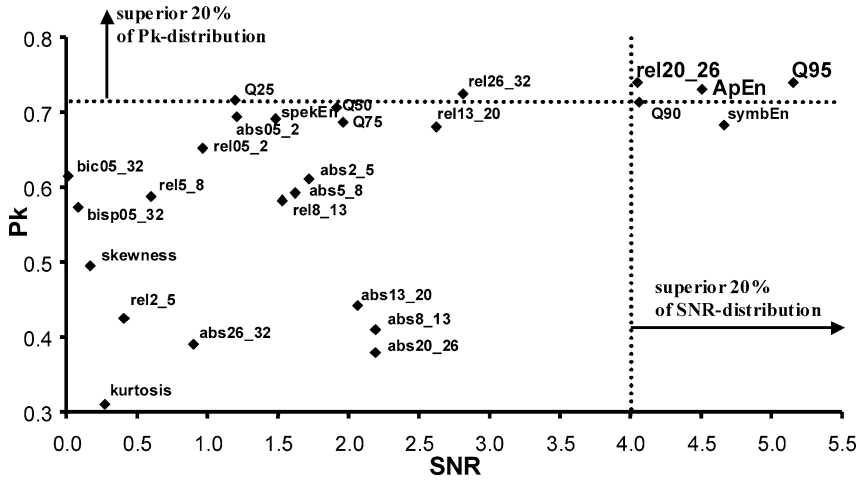
Introduction: The suitability of EEG derivations as surrogate parameters for 'depth of anaesthesia' is usually quantified only by the prediction probability Pk, an association statistic to clinical endpoints [1]. Also, few clinical endpoints are used, like consciousness vs. unconsciousness [2]. However, a high association statistic alone is not sufficient, moreover the association to clinical endpoints should ideally contain no time delay. This requires a low hysteresis, which implies a high signal-to-noise ratio (SNR) of the EEG derivations. This study investigates 26 frequently computed EEG derivations from volunteers during 17 clinical endpoints under propofol application and identifies those parameters



with highest Pk and SNR as suitable for monitoring anaesthesia.

Methods: With the appropriate ethics committee approval and informed consent from participants, we analysed 54 h EEG recorded during 2 consecutive propofol applications to unpremedicated volunteers. The depth of anaesthesia was reflected by 9 clinical endpoints at 17 different times. For the computation of the Pk-value we used the median of the analysed EEG derivation nearby the clinical endpoint. After noise estimation of each EEG derivation with the algorithm proposed by Tukey [3], we computed the SNR-value as ratio of signal variance to noise variance. The superior 20% of the EEG parameters in the Pk- and SNR-distribution were considered as suitable for monitoring depth of anaesthesia.

Results: Relative Power 20–26 Hz (rel20-26), Approximate Entropy (ApEn) and 95. Quantile of Power Spectrum (Q95) show a Pk$\geq$0.72 and a SNR$\geq$4.0 (Figure).

Conclusions: The simultaneous analysis of Pk and SNR clearly identifies the higher spectral components of the power spectrum as parameters with a robust discrimination between the derived levels of depth of anaesthesia. Newer EEG derivations like the entropy quantities do not contribute to a relevant increase in Pk- or SNR-values. The bispectral EEG derivations show low Pk- and SNR-values and are not suitable for monitoring anaesthesia.

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DEVELOPMENT OF A FULL DISCLOSURE ANESTHESIOLOGICAL RECORDING SYSTEM

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Developments in medical knowledge in the middle of the eighties led to an increasing demand for software designed for multichannel storage of ECG, blood pressures and other parameters. Issues which needed to be addressed were the number of parameters (the dataset) to be registered, the display of the parameters, the acquisition-, processing- and storing methods of the data. Specific software which met all demands was not yet developed, and the available hardware comprised stand-alone solutions using "total design" hardware with limited functionality at best. Increasing its functionality was only possible by buying new equipment. A beta-version data storage and motoring program was written by our department meeting present day demands.[1] First data records of monitor signals in the form of unprocessed original data provided reproducible digital results.

The newly developed program provided:
- Possibility of adapting the number of parameters to be registered, with digital output and plug and play performance.
- Simple maintenance of display lay-out and alarm settings
- Up to date connectivity to other hardware and software, interfaces based on universal standardization and an open architecture: *the open system*

This led to the following developments and features:
- Development of an information system (IS) with afferent and efferent data streams constructed with standard commercial available software or freeware, adjustable to several hardware platforms. (Efferent: operating the equipment; afferent: acquisition of data).
- Processing of the data in the IS when needed or wanted (adapted to the wishes of the user) and recording the data with the proper sample frequencies and automatically storage in an unprocessed form: facilitating playback with displaying all (chosen) parameters
- Bringing the transducers out of the IS facilitating changing the number and the type of parameters
- Easy adaptation of the display and alarms to the individual wishes
- Simple connection to the outside world: other computer systems, PDMS, internet, libraries, other theatres, decision support/expert systems, management systems etc. As much as possible using standard interfaces to keep things really simple.

Because of the legal problems connected to the use of efferent signals for operating equipment by software, the decision was made to concentrate on the afferent part of the IS, and to emphasize the open architecture of the system with the possibility to add new functions in the future. Avoiding the dispute about the dataset led to the philosophy of *full disclosure*: all signals and parameters available are recorded and stored in the original format.

The program, now named the AIS (the anesthesiological information system), consists of a network of locally in the monitor operated recorder programs which in connection with a local situated computer send data to 2 other servers for storage with standard network technology. During the lecture we will present a demonstration of the system.

[1] Initiated by the late Henk Ros and written by Nico van Schagen.

PATIENT DATA TRAVELLING OR PATIENT TRAVELLING WITH HIS DATA: AN OLD NEW CHALLENGE

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Introduction:

Technology allows now storage and transfert of huge amounts of patients data. This may be of great benefits for the patients and for the physicians taking care of them. Government and social insurance think that this may bring substantial economies and several nation wide programs of patient data bases or patient personnal e-records are being developed in order to bring more safety and avoid redundancy and therefore limit health expense. The objectives of course are not the same depending on the physician, scientific and quality insurance or administrative and financial points of view. Several issues are raising also, according to the proposed technology and the solutions for safety of the stored data, its privacy, reliabilty of the transfert, lifespan of the storage and its maintenance and finally medicolegal issues. Anaesthesia and Intensive Care generate usually tremendous quantities of data and need to have informations coming from other specialists or about patients previous history. The questions is also how these anaesthesia specificities must be taken in account.

Methods: we have browsed the main projects from different countries and compared the ongoing solutions and main issues and we have focussed then on the french "DMP- dossier médical personnel" or Personal Medical Record.

Results: Most of the developped countries are implementing solutions for the personal medical record. This include "trusted" remote repository of patients data readable and writable by a physician through the secure web with permission of the patient .(UK [1], France [2], Switzerland) or electronic card with more or less storage capacity, most of the time used only as key to access the remote database.(Germany, Quebec, Switzerland). Patients and physicians are reluctant to use the personnal medical record when there is poor privacy policy in the country and this is in some cases a barrier to the development of the personal medical record. Remote repositories allow more extensive database than electronic cards. No specificity for anaesthesia data were noticed in the existing solutions.

Conclusions: The idea of "DMP" is well accepted by the french people and they believe that "all their medical data and history" must be put in their "DMP". But probably the anaesthesia history must be summarized in the DMP instead of being uploaded extensively. The French National Society for Anaesthesia and Reanimation (SFAR) has published guidelines for anaesthesia recordkeeping [3]. However no guideline has not yet been proposed for the future "DMP". Reflections on minimal data set for anaesthesia records were already initiated by the ESCTAIC [4, 5] and although storage capacities have increased and improved dramatically, the question "How much data is just right" remains actual and we must now emphasize on the quality of the stored data. We think also that some "minimal" configurations readable anywere in Europe will be of great value and must be considered in the design of the "DMP". Patients privacy must be carefully considered in these systems.

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GETTING THE MOST FROM CLINICAL DATA THROUGH PHYSIOLOGICAL MODELLING AND MEDICAL DECISION SUPPORT

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Introduction: Despite the widespread use of clinical databases that enable automated storage and retrieval of patient

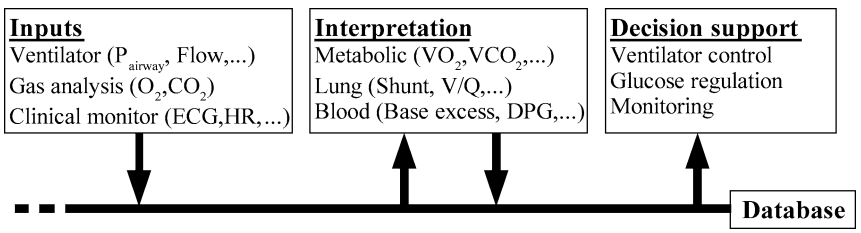

Fig. 1. Illustration of the 3 basic types of clients that connect to the database.

measurements, their implementation in supporting clinical decisions is somewhat limited. Clinicians are still faced with the difficult task of interpreting large amounts of patient data to diagnose illness and monitor recovery. This abstract presents an architecture that combines standard database technology with physiological modelling to create a clinical decision support system. The system can automatically retrieve data, interpret it using a variety of methods and assist in diagnosis and treatment.

Method: Figure 1 illustrates the architecture which is implemented, in this case, for assisting treatment of ventilated patients. The architecture includes a central database allowing data communication with three basic types of clients for data input, interpretation and decision support. The input clients enter raw data from either the clinician or by connecting directly to medical equipment such as a ventilators, gas analysers and clinical monitors. The interpretation clients, which range from simple body surface area calculations to complex physiological models of the lungs [1], are notified when new data is available in the database. This data is used by the interpretation clients to calculate more abstract values such as metabolic parameters, lung function and blood properties, which are also added to the database. Finally, the decision support clients can load both the raw and calculated data, and display it in a way that best helps clinicians diagnose the patient state and choose the most suitable ventilator settings [2].

Results: The presented modular design makes software development easier by allowing independent development of device drivers, calculation methods, physiological models and decision support systems to extend the functionality of the architecture. Implementation in the clinical environment assists clinicians by both adding a level of abstraction to raw data, to give a deeper understanding of patient condition, and offering assistance in selecting the most suitable treatment strategy.

Conclusion: This abstract presents a modular architecture combining existing database technology with physiological modelling and decision support for assisting the clinician in diagnosing and treating the patient. In doing so we illustrate the potential for building systems which not only store data, but aid in the clinical decision making process.

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TELECRITICAL CARE: THE SUTTER HEALTH SYSTEM EXPERIENCE

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Introduction: In 2002 Sutter Health System [1], a 26 hospital, 3,400 physician system in Northern California, began implementing a telecritical care system (*e*ICU®; VISICU, Inc, Baltimore, Maryland) [2] across all its intensive care units (ICUs). By the end of 2006 two remote centers will be monitoring the Sutter System's approximately 400 critical care beds, with 161 served by the Sacramento, California center. This talk will provide a first-hand report on what it is like to work as a clinician in a telecritical care setting. Additionally, it will present initial quality assurance data.

Methods: The day-to-day experience of the authors was reviewed. Quality measures from one hospital (Sutter General Hospital) were trended. These included process measures such as ICU length of stay and outcome measures such as ICU and hospital mortality.

Results: There is a consensus among the Sacramento staff that telemedicine technology can enable effective remote critical care consultation that complements care offered by traditional bedside providers and that reduces undesirable practice differences. Acceptance by bedside clinicians is variable and is the key factor that determines whether the consultant can effectively contribute to patient care. Additionally, there are several areas where improvements in the software and integration with a true electronic medical record can improve productivity of the consultant.

ICU length of stay increased slightly from 3.61 days prior to initiation of the telecritical care program to 3.73 days over the first 15 months. Over the same time interval, however, ICU mortality rate dropped from 12.0 percent to 9.8 percent and hospital mortality has dropped from 17.8 percent to 13.2 percent.

Conclusions: Telecritical care is evolving but an important role appears to be enabling standardized, high-quality practices across the critical care units of a health care system. Full implementation of telecritical care requires re-engineering of bedside roles, behavior, incentives, culture and information systems. Initial quality assurance data suggest that telecritical care is improving outcomes in the Sutter Health System critical care program.

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TELEMONITORING

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Telemonitoring is defined as "monitoring a patient at a distance". To date most applications of telemonitoring

have been concerned with the monitoring of patients at home. In these the required data is usually either entered onto a computer manually by the patient or automatically collected by attached sensors. The collected data is then sent, via an internet link, to a medical centre for analysis. The results of the analysis can be sent to the patient's doctor.

However, the remote monitoring of patients in surgery and ICU is another important use for telemonitoring. There are two main forms of this:

1) Remote telemonitoring – The clinician is remote to the hospital and data has to be sent via link in a similar manner to the home telemonitoring.
2) Local telemonitoring – The clinician is still in the hospital but needs to maintain a link with a patient.

One solution to providing a local telemonitoring link is through the use of wearable computers. These highly portable devices are about the size of a paperback book and typically weigh one kilogram. All the standard computer peripherals are used although they are usually modified to accommodate the increased portability of the system. For example, the viewer can weigh 35 g, be clipped onto a pair of glasses and yet provide a 640×480 display.

By wearing one of these systems, an anaesthetist or surgeon can obtain a "head up" display of patient variables, images (X-rays etc) or other information while still observing the patient. A key aspect of this approach is the Human-Computer interface, both in terms of optimum methods for inputting and visualising data, together with the practical aspects of carrying a computer and looking at the display for long periods of time. A wearable computer and suitable wireless network can enable an anaesthetist to monitor a number of patients, support trainee clinicians and remain mobile while still in the hospital.

The presentation will give an overview of remote telemonitoring and then introduce a method of local telemonitoring using wearable computers. As in all aspects of telemonitoring confidentiality of patient information is essential and this area will also be discussed.

AMPHI™ – AMBULANCE RECORD–KEEPING SYSTEM

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Introduction: The increasing demands for documentation and quality assurance within the Danish health service have led to the development of amPHI™-an on-line record-keeping system for the ambulance services.

The main objective of amPHI™ is to raise the quality of the treatment and thus increase the survival. The system is based on an on-line data connection between the hospital and the ambulance using a GSM-based secure telemedical network. Information regarding patient condition and treatment is registered in the field using handheld or vehicle computers. Data are sent to the hospital and made available on the local intranet.

When the patient is identified by civil registration number, the ambulance crew gets on-line access to some critical medical information registered in the patient's medical record. Which data the ambulance crew has access to are defined in advance and include previous hospitalization in the county, allergies, chronic diseases etc.

Methods: amPHI™ was installed in two ambulances as a pilot study during 2004-one ambulance dedicated to emergencies and one to interhospital transfers. Since the hospitals in the county are not yet able to handle ambulance case records in electronic form, the case record is printed upon arrival to the hospital. Dedicated printers were therefore installed in three hospitals. The ambulance crew was given a short introduction and told to use the system in all patients admitted to one of the three hospitals. Also they were instructed to revert to the paper case records if any difficulties. Data from the emergency ambulance were analysed.

Results: During the pilot study we overall registered 486 turn-outs to the hospitals with printers and amPHI™ was used in 377 patients (77.6%). In the last six months of the study there were 255 turn-outs and amPHI™ was used in 210 patients (82.4%).

In 143 cases (37.9%) the patient was identified from civil registration number by the control centre giving the ambulance crew access to the critical medical information already on their way towards the patient. Patient identification for additional 210 patients (55.7%) was entered by the ambulance crew when talking to the patient or relatives. A total of 24 patients (6.4%) were not identified.

318 patients (82.2%) had previous hospitalizations in the county. Information about allergies or chronic diseases existed for 35 of these patients.

Conclusions: The ambulance crew are satisfied with the system. They find amPHI™ easy to use and do not want to revert to the paper case records. The access to a patient's medical record is very helpful in forming a general view before selecting the treatment.

The amount of patients where the system was not used decreased during the pilot study. Some reasons for not using amPHI™ were technical maintenance, inexperienced users and insufficient coverage for data communication on the GSM network in the countryside.

POINT OF CARE (POC) TECHNOLOGY IN AN OUT OF HOSPITAL EMERGENCY SETTING: LIMITATION OF A PROMISING TECHNOLOGY

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Introduction: The Friuli-Venezia Giulia Helicopter Emergency Medical Service (FVG-HEMS), based in the Udine Hospital, is the only Region Helicopter based EMS facility, and guarantees the immediate dispatch of an Anaesthesiologists based trauma team for a population of 1.2 million people.

Some Authors [1, 2] postulated the use of a Point Of Care (POC) whole blood analyzing device for immediate on scene results in the pre-hospital emergency setting. We've decided to test the feasibility of such a device in our HEMS service.

Methods: During the test phase period (August 1 to September 30, 2002) we've intended to enrol all severe trauma patients (RTS $\leq$ 11) rescued from one of the FVG-HEMS rescue teams, namely from the main Author of this abstract.

The POC device that was chosen for this study was the i-STAT PCA (i-Stat Corporation, East Windsor, NJ, USA). The device dimensions are $20 \times 6.5 \times 5$ cm and weights 539 g. It is powered with two 9 volt off-the-shelf batteries. The factory specification states that the device is operating between 18 and 30°C.

The determination cartridges were the $EC4^+$ (Na^+, K^+, Glucose, Haematocrit) and the $CG4^+$ (pH, $PaCO_2$, PaO_2 Lactate). Both needed 60 μL to perform an analysis. They must be long-time stored at 4 °C, but may be kept at room temperature immediately before utilization [2].

The patients were blood sampled with a Heparyn treated syringe on the scene, immediately after intubation, and the blood analyzed in the cited disposable cartridges as soon as feasible according to the rescue actions priorities.

Results: In the study period 55 patients were rescued by the Author, of those 22 patients presented an RTS $\leq$ 11 on scene and may therefore have been enrolled according to the study criteria.

However in 14 cases (63,6%) the iStat device wasn't operating due to high temperature limitation. Therefore, only 8 patients were analyzed, mainly during the month of September. Some of the cited Authors [2] reported to have stored the POC device in a thermal bag. We've tried the same, but inside the Helicopter the temperature reached highs of 52°C, leading sometime to a differential of more of 25°C. The time frame between mission start and intubation of the patient was of 22,2 ($\pm$4.2) min. This was enough to raise quite often the thermal bag (and POC device) temperature to over 30°C.

Conclusions: Although the South of Europe climate is commonly considerer quite hot, and we've conducted our trial phase during summer months, we did not expected so much temperature related problems. After this trial, we've reconsidered the acquisition of the device, and contacted the producer hoping for a technical solution to our problems, but none was proposed, and we were obliged to abandon this promising technology.

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HOW TO BEST DISPLAY PHYSIOLOGIC SIGNALS AND THERAPEUTIC INTERVENTIONS

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Introduction: Traditional information displays are not designed specifically to help clinicians detect life-threatening events or manage medications. Most use a "single-sensor-single-indicator" display paradigm. As a result, clinicians must observe and integrate multiple data elements generated by independent sensors. This process of sequential, piecemeal data gathering may be an impediment to a coherent understanding of the patient's underlying physiological processes. Traditional physiological displays can be enhanced by integrating the disparate data elements with graphic representations that are consonant with clinicians' cognitive representation (mental model) of patient physiology. Such integrated graphical displays support diagnosis and treatment decision making, especially of clinical problems involving complex alterations of multiple physiological variables.

Methods: Weinger evaluated a display in which variables are displayed as histograms. When all variables are normal, the display shows a normal "horizon". Michels developed a graphic anesthesia display that organized 32 variables by organ system, showing the absolute value for each variable in relation to a "normal" reference frame. Blike mapped physiologic variables into display objects with meaningful shapes. Agutter arranged variable to mimic physiologic blood flow through the circulatory system. His display was designed using normally-shaped and uniformly-spaced

elements to create a smooth, balanced design, which allows the clinician to quickly detect change. Effkin displayed anatomical relationships and causal constraints between key hemodynamic data.

Results: Test subjects detected changes in 15% less time with the normal horizon display and an average of three minutes sooner with reference frames and ordered structure. Meaningful shapes resulted in 27% faster recognition and diagnosis of the etiology of shock. By showing nurses how etiological factors related to symptoms, subjects solved 97% of the episodes when using the new display, but only 90% of the episodes when using a traditional display. Jungk demonstrated that anesthesiologists succeeded in controlling circulatory variables 89% of the time when they used a graphic display as compared with 63% of the time when they used a traditional trend display.

Conclusions: When patient variables are clearly displayed graphically, critical event are resolved in one-third the time, diagnosis is more accurate and patient variable are better controlled. A graphic display can reduce cognitive demands during multiple events, cascading events, or when the clinician is distracted by multiple tasks in a stressful clinical situation. This savings in mental effort could translate into improved safety and in improved overall care.

CONSISTENT ERGONOMICS – A PRECONDITION FOR OPTIMAL CLINICAL WORKING SYSTEMS

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Introduction: Medical electrical equipment used in High Dependency Environments (HDEs) such as Operation Rooms (ORs) and Intensive Care Units (ICUs) should support the staff in performing the patient treatment with high quality. Industry has to prove the usability of their products, which has also become the objective of a new IEC standardization [1]. Usability takes two factors into account: the intended use of a product and the user. System ergonomics offers knowledge and methods to support usability engineering in industry in general. But within the design of medical equipment also additional aspects have to be considered to meet the complexity of clinical working systems.

Situation and Problems: The task "patient treatment in HDEs" consists of many sub-tasks which are processed on a *case layer* in different structures (e.g. treatment of a poly-traumatized patient in the Emergency Room, OR and ICU) and on a *workplace layer* in parallel (e.g. ventilation, cardio-vascular monitoring). For almost all sub-tasks medical devices are produced by a lot of highly specialized companies. These devices are designed according to patho-/physiological needs (e.g. oxygenation in lung insufficiency) and availability of technology. Each device has its own user interface claiming good ergonomic design (*device layer*). Comparing different groups of medical devices (e.g. infusion pumps, ventilators and monitoring systems) it is obvious that good ergonomic design (usability) can be achieved by quite different concepts for Human-Machine-Interaction (HMI). All the devices used in the treatment of one patient are setting up workplaces which have to be controlled by clinical staff as an entity. On this *workplace layer* the ergonomic design is very poor: Devices (including their display and control panels) are scattered all over the workplace. Vital parameters are hidden among unimportant details. Five and more different concepts for HMI are not seldom. Human errors are pre-programmed. Considering the entire *case layer* the situation is even worse.

Goal: We need a top-down concept for a consistent ergonomic design on all system layers: From medical cases to clinical workplaces and specific technological devices.

Concept: We are using the Task-Process-Task-Model (TaPTa) to analyse complex working systems in an hierarchical and recursive way [2]. A task is separated into sub-tasks according to the process planning. The question "HOW do we complete a task?" leads us to more detailed processes and sub-tasks (lower system layers). The question "WHY are we doing things?" leads us to more aggregated tasks (higher system layers). We propose to link ergonomic aspects to the TaPTa-Model and its layers. Thus we can define ergonomic guidelines for different system layers:

For the case layer: Guidelines for the patient treatment and the organizational design of ORs and ICUs (e.g. ground-plans, necessary staff structure, functions of workplaces, logistics etc.).

For the workplace layer: Guidelines for the workplace design including its equipment, structure, overall HMI, surrounding (e.g. light, colours, climate, noise) etc. [3].

For the device layer: Guidelines for specific devices including their functions, HMI, physical design, service, training etc.

On all system layers ergonomics considers the task (defined by the patient's treatment), the processes to complete the task, the usage of technical structures and the required staff (users). The question "HOW do we realize the ergonomic guidelines?" leads us to more detailed system layers. The question "WHY do we need a display, device, workplace or OR" leads us to higher system layers with more extended (but also general) rules for an ergonomic design.

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THE PROMISE OF COMPUTER – AIDED ERGONOMICS IN INTENSIVE CARE

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Introduction: Computer-Aided Ergonomics is a novel method, which is quickly establishing itself in the advanced industry [1, 2]. This paper describes the promise of this technology for assessment of working situations typical for intensive care.

Methods: In the present case we use the AnyBody Modeling System, which is based on inverse dynamics and recruits muscles by a minimum fatigue criterion [3]. This enables the system to handle very complex models on ordinary personal computers. The system computes individual muscle forces and joint reactions, and therefore allows for comparison of loads on the body in different postures and working situations.

Results and Conclusions: Figure 1 illustrates a typical forward-leaning working posture. As indicated by the muscle thicknesses, the model is recruiting primarily the hamstrings and spine muscles to balance the effect of gravity. A continuous variation of the angle between thighs and thorax from 0 to 90 degrees reveals the effect of the posture on body loads such as muscular activity and pressure on the spinal disk between L5 and sacrum as illustrated in Figure 2. Such investigations allow for detailed assessment of the influence of the design of the intensive care environment on the performance and safety of the personnel.

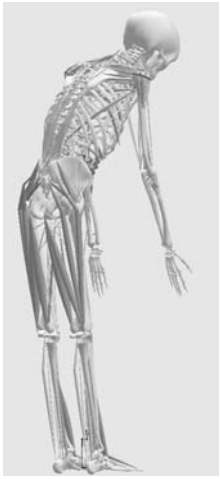

Fig. 1. A forward-leaning working posture.

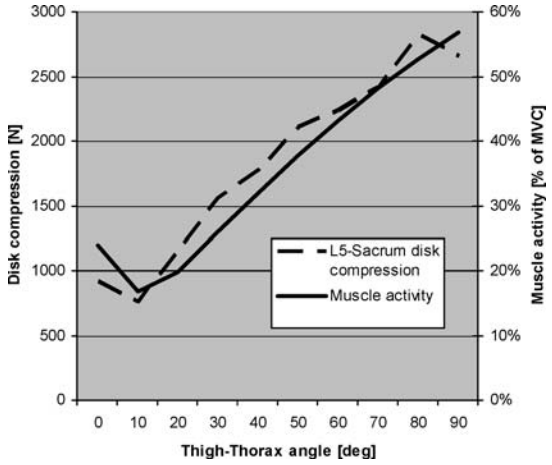

Fig. 2. Effect of posture on body load.

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POINT-OF-CARE CONNECTIVITY AND INTEROPERABILITY: AN INTERNATIONAL STANDARDS UPDATE

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Introduction: State-of-the-art medical technology applications utilise interoperation among multiple point-of-care medical devices including related information systems. For complex intensive care and anaesthesia monitoring scenarios, connectivity and interoperability requirements typically comprise real-time operation and plug-and-play system configuration capabilities. The term "Real-time" indicates that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second. "Plug-and-play" means that all the clinician has to do is make the connection – the systems automatically detect, configure and communicate without any other human interaction. To address these requirements, CEN

standards ENV 13734/35 – known under the acronym "VITAL" – and related IEEE 1073 documents, which started their development more than one decade ago under the title "Medical Information Bus", were and are getting aligned and extended in the ISO 11073 standards family.

Point-of-care test devices like glucose meters or blood gas analyzers – usually distributed among multiple hospital locations – are introducing quite different communication requirements. Typical operation avoids situations in which a patient might be connected to several devices reporting related or the same type of data. However there is a strong demand for utilising existing information system infrastructure as far as possible. Accordingly the Connectivity Industry Consortium (CIC) – a joint diagnostic industry and user consortium – developed a standard for point-of-care (POC) connectivity based on existing IEEE 1073 and HL7 V.2.5 concepts which was first published as AUTO6-P draft by the end of 2001. ANSI NCCLS has subsequently approved and updated the original draft and issued the resulting POCT1-A standard.

Status quo and Ongoing work: POCT1-A is already in the phase of implementation by a number of major manufacturers. Specific emphasis is on high-level quality control. Guidelines like the new Quality Assurance Guideline ("RiliBÄK") issued by the German Medical Association (GMA) require that results from POC test devices are subject to quality control and documentation procedures equivalent to clinical lab operation. Hence remote POC devices have to be connected to clinical networks to minimize control and documentation overhead. POCT1-A is the adequate and practicable standard to be used in such applications.

The ongoing process of adopting NCCLS POCT1-A as a formal international ISO, CEN and IEEE standard, however, had to overcome major administrative obstacles. It is embedded in the current development of the CEN ISO IEEE 11073 family of standards which was enabled by the 2002 ISO/IEEE pilot process agreement. Parallel ongoing CLSI (the new name for NCCLS since 2005) modification and extension efforts aim at a revision of the POCT1-A standard to be reflected on CEN, ISO and IEEE levels. To speed up CEN ISO/IEEE adoption, the revised standard will be published by ISO TC 215 using the original POCT1-A document in a fast track process. First formal results are expected for late 2005.

MICRODIALYSIS – A SAMPLING TECHNIQUE TO MEASURE BIOCHEMISTRY DIRECTLY IN THE TISSUES

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Introduction: Microdialysis is a technique for sampling the chemistry of the interstitial fluid of tissues and organs in animal and man. A dialysis membrane at the distal end of a microdialysis catheter functions like a blood capillary. Chemical substances from the interstitial fluid diffuse across the membrane into the perfusion fluid inside the catheter. The fluid is collected bedside ready for chemical analysis. The availability of modern analytical techniques has made the microdialysis catheter a "universal" biosensor capable of monitoring essentially every small molecular compound in the interstitial fluid of endogenous as well as exogenous origin.

Today microdialysis is a standard technique in physiological and pharmacological investigations and an emerging technique in the field of intensive care monitoring. It provides crucial information about how seriously cells are affected by for example ischemia, hyperemia, trauma, hemorrhage, vasospasm as well as various physiological, pharmacological and surgical interventions during intensive care.

Chemical markers of tissue biochemistry: The lactate/pyruvate ratio is a well-known marker of changes in the redox state of cells caused by e.g. ischemia. The use of a ratio between two analytes abolishes the influence of alterations in catheter recovery as such changes influences lactate and pyruvate to a similar degree. Therefore the lactate/pyruvate ratio can be used to compare the redox state of different tissues in one individual as well as between different individuals. The normal ratio is essentially the same in all tissues i.e. 15-20 while a ratio above 25 is a sign of tissue ischemia.

Glycerol is used as a marker of cell damage as it is an integral component of cell membranes. Loss of energy due to ischemia leads to an influx of calcium into cells, activation of phospholipases and eventually to a decomposition of cell membranes, which liberates glycerol into the interstitial fluid.

New concepts in data analysis: Microdialysis provides a new bedside variable, adding to the already massive amount of information that has to be understood and acted upon by the intensive care staff. It requires more than "standard" knowledge of tissue biochemistry and it becomes truly useful only when it is integrated with already existing bedside information. In order to provide such an integration we have developed a new software, ICU-Pilot, collecting data from essentially all bedside devices. It has a unique user interface allowing real time comparisons of different measurements, which greatly facilitates the integration of tissue biochemical data into routine intensive care.

BASE EXCESS AND CRITICAL CARE IN THE PAST AND IN THE FUTURE

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The importance of acid-base status on the treatment of diseases has followed the development in blood gas

measurement. In 1908 L.J.Henderson published his work on the balance between acid and bases that affect the neutrality of blood. From the law of mass action, he expressed the concept of buffers by an equation included carbon dioxide, carbonic acid, bicarbonate and the constant of dissociation. The pH scale was invented by S.P.L. Sørensen in 1909 and in 1917 K.A.Hasselbalch, influenced by pH nomenclature, made a logarithmic rearrangement of the Henderson equation, and thereby the well known Henderson-Hasselbalch equation. The equation was written to permit the calculation of pH from the measurable total CO_2. The next step happen 35 years later, during the Polio-epidemic, when P. Astrup in 1952, using the Henderson-Hasselbalch equation, introduced the estimation of pCO_2 based on pH measurements at different but known pCO_2. This method made it possible to diagnose respiratory acidosis, and thereby the start of intensive care and ventilatory treatment. In 1958 J.W. Severingshaus introduced the CO_2 electrode for direct measurement of pCO_2. With measurement of pH as well as pCO_2 the Henderson-Hasselbalch equation was now used to calculate the concentration of bicarbonate.

Base excess and the acid-base nomogram: Base excess was introduced by Ole Siggaard-Andersen for almost 50 years ago. While pH and pCO_2 are directly measured, the metabolic component, defined as Base excess, is calculated from pH and pCO_2 using the Henderson-Hasselbalch equation and the Van Slyke equation. By using base excess the acid base status is made simple and clinical useful. A nomogram including pH, pCO_2 and Base Excess (i.e. the Siggaard-Andersen ACID-BASE Chart) illustrates the acid-base status of the arterial blood. The chart shows normal values as well as values to be expected in typical acid-base disturbances, i.e. acute and chronic respiratory acidosis and alkalosis, and acute and chronic non-respiratory (metabolic) acidosis and alkalosis. Today critical care units use point of care blood gas analyzer with graphic decision support i.e. the acid-base chart. The modern blood gas analyzer also includes measurements of several parameters t.ex. Lactate and electrolytes incl. potassium and chloride. This multi parameter measurement may add new entities in acid-base disturbances in the critical care setting, t.ex. "Dilutions-acidosis" observed after infusion of normal saline, but not after ringers lactate.

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COMBINING SCENARIO ANALYSIS AND METADATA TO ANALYSE PATIENT WORKFLOWS FOR COMMON DISEASES

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Introduction: Clinical chemistry is a central part of every hospital. With the increasing abilities of modern medicine the hospital laboratories have lost their individual forms and turned into fully automated highly computerised work places. Even though automation makes laboratories more efficient most hospitals suffer from yearly growth in number of blood samples and results delivered. Rates of 7–10% increase per year are normal for European hospitals. Little work has been done to connect patient populations to the actual process during the hospital stay. Following diagnostic efforts still remains complicated and tedious, often just secondary result of clinical studies.

By applying metadata analysis the authors have been able to demonstrate, that isolation of patient populations across departments and local hospitals is possible and enables analysis of clinical chemistry usage.

Methods: From the LIS (laboratory information system) samples of patients are drawn with one single diagnosis. The diagnosis, extracted from the Danish patient register, is matched to the hospital information system. For the initial trials all patients with more than one diagnosis or uncertainty about the diagnosis were excluded.

One year of patient data for one diagnosis with all results was extracted, typically 1000–1400 cases. The cases were combined with all data from the other sources to construct metadata sets. During this process the datasize typically changes from 1.2 MB to 36.4 GB of data. On a UNIX computer running STATA and R along with specialised visualisation routines the data was mined for organisational relations to number and timing of samples.

Visualisation was then made possible by defining reference intervals for each biochemical parameter and its changes during the hospital stay. Together with a clinical reference group the visualisation of pathologic, normal and indifferent values by department was made possible. Patient groups were compared to each other with regards to other confounders.

Results: Despite the use of evidence based medicine the influence of department structure and organisation is obvious. Number of blood samples varied by 48% and number of normal results by more than 320% in the same patient group. Obviously the intention to use rational diagnostic

measures is often covered by computerised systems. In all the extreme cases of unnecessary blood sample collection hospital information systems were identified as the main cause. By identifying scenarios in different departments the necessary countermeasures were quite simple changes in instructions or daily rhythm.

Conclusions: Further work is needed to allow analysis of metadata across hospitals and departments. Clinical biochemistry departments need to join the development and distribution of such tools. In simple diagnosis such as pneumonia the difference is striking and invites to investigate the role of information technology as a negative factor in the cost development.

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NETWORK CONNECTED POCT ANALYZERS – REPORT OF A RADIANCE IMPLEMENTATION

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Today's physicians taking care of critically ill patients now require that laboratory results are made available in realtime and if possible, at the patients point of care. Many new testing devices have been developed to address this need; however hospitals often implement such distributed devices with little or no attention to the information technology requirements. (Kenneth E. Blick, 2000)

RADIANCE offers a flexible connectivity solution for blood gas analysers at the point of care. Also non-Radiometer analyzers can be connected, providing a common software platform for data management functionality. Protocol support includes standards ASTM, HL7 POCT-1A and nonstandards like LIS (Bayer) as well.

Our motives for implementation of a POCT device network

- *Remote device control*. facilitating online troubleshooting, service and maintenance functions
- *Paperless quality management*. Transmission, central storage and evaluation of quality control and calibration data, legal documentation according German RiliBÄK.
- *Sending of patient test results.* connection to our online anaesthesia documentation system NarkoData.

Clinical environment: The "Klinikum der Universität München" has 2.479 beds, cares for 86.900 inpatients and performs 46.000 anaesthesias per year.

RADIANCE set up: Due to historical reasons three RADIACE servers are implemented. The department for Anaesthesiology runs one system connecting 16 analysers (ABL 5xx, 6xx, 7xx Rapidpoint 400, 800). Connection is implemented on basis of the clinical network wired and wireless (WLAN). A side by side VPN connection to Radiometer is realized for remote support.

We are currently running software 2.3.

Experience: Since one year the RADIANCE system is running very stable without extraordinary amount of work. Information technology can help you unburden your busy testing environment by automating testing procedures, quality control, documentation and data management. Not to mention enabling control of decentralized analyzers from a central location.

Message to vendors of poct devices: Accuracy and precision are no longer most important, information technology and networking issues have become the determining factor. For those vendors not providing state-of-the-art, open IT solutions along with their devices, the future looks black.

ADAPTIVE TEAM COORDINATION IN ANAESTHESIA TEAMS: MEASURES FOR DIAGNOSIS AND IMPROVEMENT

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Introduction: Depending on situational demands, teams should use different coordination mechanisms, such as explicit vs. implicit, impersonal vs. personal and hierarchical vs. lateral coordination. Based on results from studying team coordination in different work phases in cockpit crews (Grote et al., 2004), we analyzed team coordination during anaethesia induction, with the aim of identifying adaptive coordination patterns. We hypothesized that high standardization should coincide with high implicit coordination and little leadership behavior and little heedful interrelating, while high task load should coindice with high heedful interrelating, high implicit coordination, and little leadership behavior.

Method: We analyzed 23 teams during anaesthesia induction, using indicators for different coordination mechanisms:

– explicit (resources are spent on coordination as such) vs. implicit coordination (actions are coordinated without extra resources based e.g. on a common understanding of the situational demands) (Entin & Serfaty, 1997);

– leadership (one person undertaking coordination as his/her task) (e.g. Yukl, 1989);
– "heedful interrelating" (an attitude to teamwork, where the individual acts with constant awareness of the conditions required to succeed as a team) (Weick & Roberts, 1993).

Results: Our results support the hypothesis for different work phases regarding standardization, but not for task load, which may be due to the fact that routine inductions were observed. Also, there was an overall higher level of implicit coordination than expected given the overall low degree of standardization. This finding is in agreement with other studies showing that implicit coordination is the preferred operational mode in medical teams (e.g. Xiao et al., 2001; Heath et al., 2002). Unfortunately, no empirical links with team performance could be established as the expert rating used as performance measure did not differentiate sufficiently between teams.

Conclusions: Currently, a study is implemented, which attempts to verify the results and to establish a link with performance in order to improve the diagnostic value of the behavioral categories. Performance is measured by means of a number of reaction times in relation to the occurrence of non-routine events. Also, the video-recordings are used for feedback interviews with the team members using the critical decision method (Klein et al., 1989), which can be considered as a first step towards more systematic training of team coordination.

RISK MANAGEMENT IN MEDICINE: A CHANGE IN CULTURE

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Team performance can be seen as the product of skills and technology involved multiplied by the behavior of the team members. Accident investigation in aviation shows proof of the absence of consistent and adequate team behavior in critical phases in the majority of the accidents and incidents studied. It is mostly not the lack of skills, but rather the failure of behavior relevant to team performance within a group that contributes significantly to a mishap. Helmreich and Schaefer found similar causes for error in the operating room [1].

Industry has invested heavily into developing technology and technical training. A lot of new monitoring systems have been introduced in the field of anesthesia and emergency care, without any impact on the number of critical incidents. The primary focus of training courses in the field of medicine, such as the ATLS, ACLS, PALS, etc., is still primarily an accumulation of personal technical skills.

The area of systematically developing critical behavior standards and training tools to implement such standards has been neglected in most professions. In aviation, driven by the grim outlook of expecting a major air disaster weekly after the turn of the 20th century, behavioral training was developed, implemented and, only recently, enforced by law. Human factor experts note that medicine has tended only to focus on technical proficiency rather than the dynamics of human interaction, and, because of this, the medical profession is beginning to call for more attention to the latter.

In safety sensitive cultures, such as operative or emergency medicine, information flow is critical. Ideas and concepts must be actively sought, discussed, and evaluated with all members of the team no matter what the status is of the person having such information. In view of the fact that communication is the heart of every team's activity, it is surprising how little attention this process factor has gained in the medical literature [2].

Most behavior is learned, being shaped by such factors as socio-cultural background, education, company or hospital culture, and an internal value system. Communication in a team is a function of the attitudes displayed, and attitude is a function of the value system of the individual. This in turn has to do with ones concept of self or of others and, thus, with the motivational structure of the individual. Although these interactions are complicated, the effects of these links are evident in our daily lives; especially in the operational environment of a severely injured patient. Thus a skilled professionalism is not only required in the technical area of anesthetic skills, but also in the area "nontechnical skills".

During the course of medical training there is much pressure to acquire competence in a broad specter of medical knowledge and the anachronistic belief may still persist that once this has been accomplished, the task is mostly complete. Those with experience, however, know that this is only the beginning. Clinical acumen comes from the constant honing and refining of our skills, especially in the cognitive sphere. Perhaps the reason why excellent clinicians are less able to articulate what they do than others who observe them is because, traditionally, there has been little emphasis on developing insight into the cognitive aspects of decision-making or the deeply hidden elements that underlie our mental deliberations [3, 4]. Therefore, to systematically develop methods for identifying important attitudinal links, improving relevant nontechnical team skills, enhancing the appropriate attitudes, and generally learning about this area, were all considered to be important steps for improving patient safety.

The following dimensions are always present in successful teams.

- Maintenance of team structure and climate
- Application of problem solving strategies
- Communication within the team

- Execution of plans and management of the workload
- Improvement of team skills

We must place a strong emphasis on caregiver interactions. Health care is not delivered by individuals in isolation, even though our education, training, and testing seems to be based on this assumption. Good interactions amongst members of a health care team can have great potential for preventing errors. However, health care contains many hierarchical, territorial, and other impediments that impede communication and cooperation and create or compound errors.

It is through the development of human potential that we will be able to strive for and to achieve the highest level of safety, service, efficiency, and well-being.

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INFORMATION IMPROVES RISK MANAGEMENT DURING A CRISIS

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Introduction: Patient safety in acute care settings like the operating room and intensive care units rests on physicians' ability to make quick and accurate decisions. During patient monitoring, clinicians are presented data directly from sensors (oxygen saturation, blood pressure, and airway pressure). To detect life-threatening events, clinicians extract patterns from the data to make informed clinical decisions. Modeling combines sensor data and reveals patterns that might not be detectable when only sensor-based variables are available. Because they minimize the mental transformations required to make use of sensor-based variables, model-based visual presentations could enhance the clinical value of basic sensory measurements. In addition, integrating multiple discrete measures into patterns can make complex systems appear simpler, improving the user's perception of the patient's status.

Methods: Thirty six anesthesiologists underwent 15 min of training on the use of a graphic cardiovascular display. Half the subjects viewed both the traditional and the graphic cardiovascular display and the other half viewed only the traditional monitor while managing simulated critical events. A second study was conducted with 24 anesthesiologists using a drug management display. In a third, 19 anesthesiologists used a pulmonary display to manage adverse respiratory events.

RESULTS: When the display was used, there was a significant improvement in the time to detect and treat myocardial ischemia and SpO2 was higher and the CVP was closer to its pre-event baseline. The average performance ranking for those who used the cardiovascular display was 5.75 compared to 11.3 for those without the display (1 = top performer, 16 = worst). Subjects who used the drug display managed drug delivery more effectively by keeping heart rate and blood pressure closer to normal, reducing the rise in heart rate and blood pressure associated with painful surgical manipulations and the fall in heart rate and blood pressure associated with drug overdose. The average time to begin treatment of an obstructed upper airway was 1.6 min shorter for the subjects that used the pulmonary display. Use of the display significantly reduced the clinician's mental demand, frustration level, and effort, and enhanced their perceived clinical performance.

Conclusions: When the cardiovascular and pulmonary displays were used by anesthesiologists, the evolution of myocardial ischemia was detected three times faster and an obstructed endotracheal tube was treated 40% faster. These findings support the hypothesis that graphical presentation of clinical information improves clinicians' ability to detect, diagnose, and treat cardiovascular events and improves drug management in the operating room.

EVALUATION OF GRAPHICAL SYMBOLS USED IN INTENSIVE CARE UNITS (ICU): COMPREHENSION AMONG USERS IN DIFFERENT COUNTRIES

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Introduction: Modern medical devices and their user interfaces apply increasingly more graphical symbols to convey information. Previous researches have indicated some advantages of graphical symbols in conveying information: (a) high visual impact to transmit information effectively; (b) compact information which occupies less space on products; (c) information independent of national languages, etc [1–3].

The advantages of symbols are becoming more important for global marketing of complex medical devices. However, researches showed that symbols can be differently comprehended among users in different countries [4, 5]. Although standards and technical reports have been issued regarding the application of graphical symbols for use on medical devices (e.g. EN 980: 2003 *Graphical symbols for use in the labelling of medical devices*; IEC 60878: 2003

(draft) *Graphical symbols for electrical equipment in medical practice*; ISO 15223: *2000 Medical devices – Symbols to be used with medical device labels, labelling, and information to be supplied*), few studies have been published regarding evaluating the effectiveness of symbol in different countries. If safety relevant symbols are not correctly understood, use-related risks for the operator or patient may be provoked. These risks should be analysed and controlled according to the requirements of ISO 14971 and EN IEC60601-1-6, [6, 7].

Purpose: To evaluate the comprehension of symbols used in the intensive care units (ICU) among users in different countries and to identify potential problems with their application.

Method: Different criteria can be used to evaluate graphical symbols: noticeability, legibility, comprehensibility and suitability for learning [8]. For symbols used in medical areas, the comprehensibility should be the most important one.

The comprehension test method recommended by ISO 9186: 2001 was applied in the study [10], with the open-ended "free definition" task in the test. The participants were presented with the symbols and were instructed to write down their own opinion on the meaning (the response) of the symbols freely. Two rounds of the test were separated: the first round was the comprehension with a *global* context which showed the general product type or the general use environment; the second round was conducted with a *fine* context presented additionally which showed the direct application environment (e.g. with other possible symbols together). Totally 16 symbols used in the intensive care areas and in the operation theatre were tested. 13 of these symbols were chosen from the draft of the IEC 60878 TR Ed. 2.0: 2003 [8]. The other 3 were taken from products of different manufacturers.

Two groups of participants participated in the test: 20 volunteer German nurses and doctors and 13 volunteer Chinese nurses and doctors working in the intensive care units. The responses of all participants were independently assigned by 3 judges into 7 categories according to the criteria specified in ISO 9186. The final score of a symbol is also obtained by summing and weighting the percentages of responses in the different categories, according to the formula recommended in ISO 9186. It reflects the comprehension of the symbol.

Results: The comprehension scores are generally low in both countries: In China, the average comprehension score is 32.2 (SD = 30.3) for global contexts and 48.2 (SD = 28.9) for fine contexts; In Germany, the average

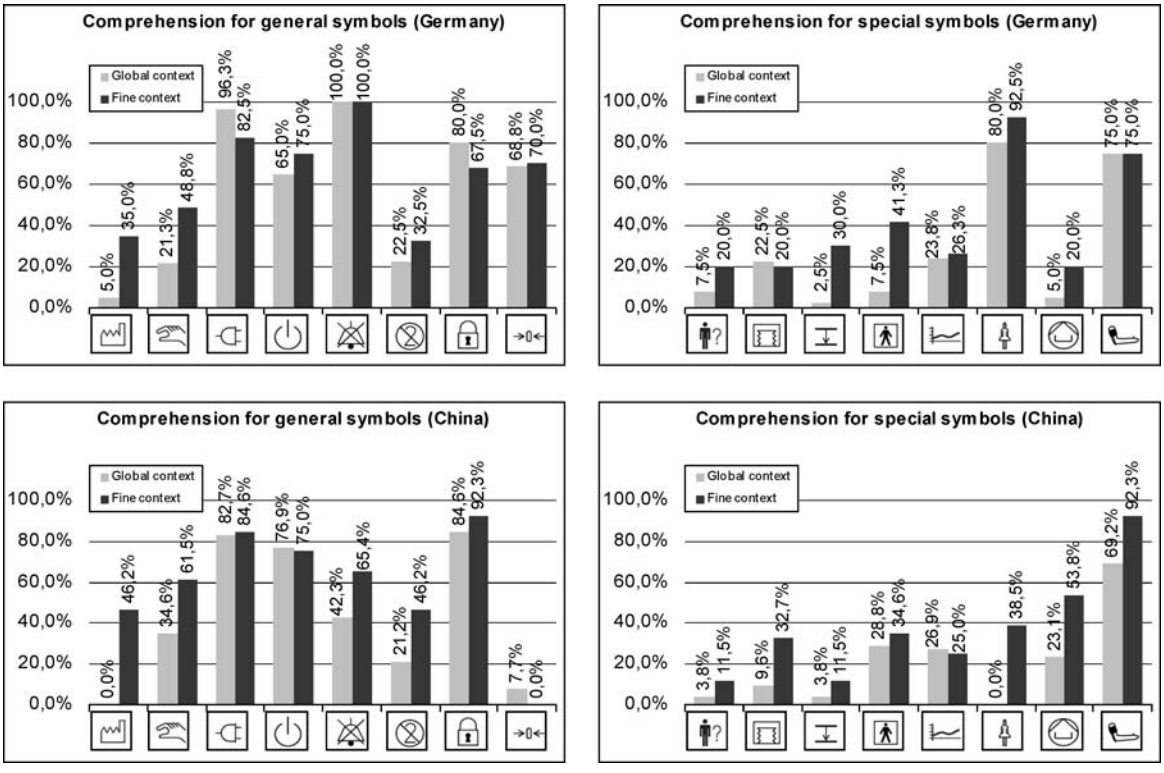

Fig. 1. Symbol comprehension among users in Germany and in China.

comprehension score is 42.7 (SD = 36.3) for global contexts and 52.3 (SD = 27.7) for fine contexts. Half of the symbols reached a comprehension score higher than 67% (the acceptance criterion specified by ISO 3864 [11] for safety-relevant symbols) in Germany but only 4 symbols reached this level in China. If the criterion of 85% specified by ANSI Z535.3 [12] was considered, only three symbols (both in China and in Germany) would be accepted. Some safety-relevant symbols, for example, the symbols for "Date of manufacturing" and "Don't reuse" reached a very low comprehension score in both countries, which suggested potential problems with application of these symbols in practice.

Further analysis was conducted to reveal differences in symbol comprehension between the two countries. The ANOVA analysis showed, neither with global context nor with fine context, the comprehension scores were significantly different for participants in China and Germany [$F(1, 28) = 0.878$, $p = 0.357$ for global context, $F(1, 28) = 0.186$, $p = 0.669$ for fine context]. The result implies that the cultural differences of participants in these two countries have no significant influence on the comprehension of the graphical symbols used on medical devices in ICU area.

It is deduced that the experience with graphical symbols would significantly influence their comprehension. Further ANOVA analysis revealed the influence of this factor. In test, we used two types of symbols: The *general* symbols are those widely used in different medical products (not only in ICU); The *special* symbols are those dominantly used in ICU area. The general symbols can be more frequently experienced by users when they work. The ANOVA analysis showed that either with global contexts or with fine context the comprehension scores of general symbols were significantly better than those of special symbols [$F(1, 28) = 5.519$, $p = 0.026$ for global context, $F(1, 28)=5.585$, $p = 0.025$ for fine context]. The result implies that the experience with the symbol use may have significant influence on the comprehension of the graphical symbols used on medical devices in ICU area.

The study results implied that not the cultural background of the users but their actual experience with the use of the symbols significantly influenced their comprehension. For effective symbol application, beside the well design and selection of relevant symbols to convey specific information, training should be a very effective way. This would be a situation for symbol application in medical area in general.

Conclusions: Summarizing the results the following conclusions can be reached:

- The comprehension of the graphical symbols tested in both countries is very poor. Half of the symbols (in Germany) or 4 symbols (in China) reached the acceptance criterion of 67% specified by ISO 3864. But only three symbols reached the acceptance criterion of 85% of ANSI Z535.3 in both countries;
- Statistical analysis did not show significant difference in symbol comprehension between participants in the two countries. The test results imply that cultural difference of the users have no significant influence on the symbol comprehension;
- Other factors, especially the experience with using of specific symbols significantly influence their comprehension among target users. This means that training would be an effective way to compensate the weakness of symbol comprehension in practice. Symbols should be learned by target users to ensure their application effectiveness.

Based on these conclusions, it is suggested that medical device manufacturers should be careful in applying symbols to convey safety-relevant information on their devices. Special measures should be incorporated in medical device user interface design, such as online prompts to indicate the meaning of the symbols, to reduce the risk of misunderstanding, as well as to encourage user's learning in the use process.

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TREAT–A SYSTEM FOR BALANCING ANTIBIOTIC TREATMENT AGAINST DEVELOPMENT OF DRUG RESISTANCE

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Introduction: Covering antibiotic treatment, matching in-vitro susceptibilities of subsequently isolated pathogens, reduces overall fatality rate of severe infections with adjusted odds ratios varying between 1.6 and 6.9. [1] In the same studies, 20–50% of patients were given non-covering empirical antibiotic treatment. The construction of a system, TREAT, that could advice on antibiotic treatment, thus reducing non-covering treatments would therefore be advantageous, provided this can be done without major increases in the cost of antibiotics, in the rate of side-effects and in particular in future resistance due to excessive use of broad-spectrum antibiotics.

Methods: A Causal Probabilistic Network (CPN) was developed to describe the diagnosis, treatment and prognosis of bacterial infections. For each patient decision theory was used to balance the expected benefit of the treatment, mainly improved survival, against the cost of drugs, side-effects and future resistance. Calibration to a given hospital was achieved through calibration databases, that for example would describe local resistance profiles and prevalences of pathogens or the local availability and cost of antibiotics. The TREAT system consists of the CPN, and of code linking it to a user interface and to the hospital's IT infrastructure [2].

Results: The TREAT system was tested in two clinical trials in hospitals in Germany, Italy and Israel. The first trial was a non-interventional trial, where TREAT was run in parallel to the clinical decisions, but where the advice of TREAT was not made available to the clinician. Among 1203 patients included in this study, TREAT prescribed covering antibiotic treatment significantly more frequently than physicians (70% vs. 58%, OR 3.67, 95% CI 2.17–6.22) using less broad-spectrum antibiotics at half of physicians' antibiotic costs.

The second trial was a controlled, randomized interventional trial, where 15 wards and 2326 patients participated. Clinicians in the study arm were given access to the advice from TREAT, but were not obliged to follow it. The rate of appropriate antibiotic treatment was higher in intervention vs. control ward patients (73% vs. 64%, OR 1.48, 95% CI 0.95–2.29). Length of hospital stay, costs related to future resistance and total antibiotic costs were significantly lower in intervention wards.

Conclusions: The TREAT decision support system has the potential for improving coverage and at the same time reduce the cost of treatment, as shown by the non-interventional trial. The interventional trial showed that some of the potential may not be realized because of non-compliance of the clinicians, but that a significant positive effect still remains.

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GLUCOSE REGULATION IN THE ICU USING A CIS

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Introduction: Until the late 1990's stress hyperglycaemia was considered a physiological and beneficial defense mechanism of the human body [1]. The landmark study by Greet van den Berghe changed all this [2]. However, translation of these recommendations into daily clinical practice in our unit by conventional means proved to be difficult. In response to this, a guideline to strictly regulate the glucose levels of our patients was developed. In order to test if compliance to the guideline could be improved, the guideline was subsequently incorporated in the Clinical Information System (CIS, MetaVision®, iMD-Soft, Tel Aviv, Israel) [3].

Methods: The study consisted of 4 periods in a 'before-off-on -off' design: before guideline implemenation, guideline available only on paper, guideline incorporated in CIS, guideline available only on paper. Primary outcome

parameter was the time the patient spent in target range (4.0–7.0 mmol/L).

Results: The length of time that patients' glucose levels were within target range (4–7 mmol/L)) before implementation of the guideline was 22.04%. With paper implementation of the guideline this increased to 44.25%. A further improvement was seen for the CIS period to 53.49%. The post intervention group the time spent in target range dropped significantly: 42.29%.

Conclusions: The increasing evidence that stress hyperglycaemia is harmful for critically ill patients has created an increased interest in glucose management in Intensive Care medicine. Guidelines are usefull in optimising the glucoseregulation, a further improvement can be achieved by incorporating the guideline in a CIS.

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INTRODUCING COMPUTERIZED ALERT SYSTEMS INTO CLINICAL PRACTICE IN THE OR AND ICU

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Computerized clinical decision support systems increase the value of electronic medical records by linking knowledge and patient data to generate alerts and reminders. These tools can enhance human vigilance, prevent infrequent but predictable slips and errors, and improve patient safety. With the advent of commercial products that allow users to create customized alerts, experience with decision support systems in anesthesia and perioperative medicine will grow.

We currently use a commercially available tool (Event Manager, Metavision, iMDSoft, Israel) to follow and alert clinical staff of various physiological parameters and combinations of physiological data with diagnostic and drug order data. The Event Manager is available in both the Anesthesia Information Management System (MVOR, iMDSoft) and the Clinical Information System for Intensive Care Units (MVICU, iMDSoft). We describe how the Event Manager is programmed, illustrated with examples from the OR and ICU.

These include administrative reminders during anesthesia and an alert for the detection of separation from cardiopulmonary bypass during cardiac surgery triggering a 'turn-on alarms' message. In the ICU examples of these 'events' include an alert for a low potassium value, an alert for persistent decrease in oxygen saturation that does not trigger the conventional monitor's alarm, an alert for performing a chest x-ray following central line placement, anticoagulants following trauma, institution of thyroid replacement therapy in hypothyroidism, administration of corticosteroids in sepsis. Other nursing-related events include Glasgow Coma Scale determination after admission, the Norton scale for the prevention of pressure sores, and a reminder for IV line set changes every 96 hours.

Challenges include appropriate selection of events, the requirement for a rich source of clinical data, the need for ongoing rule maintenance and updating, the problem of time delay for critical intraoperative events, the risk of alert overload, the need for outcome measurement, and the necessity for clinician involvement in the selection, design and implementation of these 'events'.

INSTANCE-BASED REASONING FOR SEVERITY-OF-ILLNESS SCORES

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Introduction: Severity-of-illness scores are used for a variety of clinical and management tasks. Two scoring systems in Intensive Care are the Acute Physiology and Chronic Health Evaluation (APACHE) II scoring system [1] and the Simplified Acute Physiology Score (SAPS) II [2]. Both systems summarize a patient's condition based on physiologic parameters from the first 24 h of stay at the Intensive Care Unit (ICU). The scores can be converted into an estimated probability of hospital death using an associated *logistic regression* (LR) model. This has two drawbacks. First, the LR model builds on various assumptions that are questionable for most clinical scoring systems. Second, the parameters in the model are estimated from a specific study population. When applied to a different population, these parameters may lead to unreliable predictions.

Instance-based reasoning (IBR) is a prediction method from Artificial Intelligence that overcomes these drawbacks. This method estimates the probability of death based on the outcomes of patients that closely resemble the new patient. We

studied the use of IBR as an alternative to LR in scoring-based prognosis.

Methods: Data were provided by the Dutch National Intensive Care Evaluation (NICE) register [3], which contains information on admissions to Dutch ICUs. The first dataset (1559 admissions from seven hospitals) was used for development of IBR estimators; the second dataset (1868 admissions from three hospitals) was used to validate them.

We developed various IBR estimators, based on different (combinations of) predictors, e.g. SAPS II score, APACHE II score, APACHE II score + diagnosis category etc. In total, eight IBR estimators were developed. All IBR estimators were constructed with an extension to the kernel-weighted k-*nearest neighbor* (NN) algorithm. In contrast to most *k*-NN algorithms, in our algorithm the number of neighbors is determined by the density of the neighborhood. In sparse areas of the instance space, more neighbors are used. For details of the algorithm, we refer to [4].

Results: The performance of the IBR estimators was measured by the Area Under the ROC curve (AUC). The AUC for the IBR estimator based on the APACHE II score was 0.784 on the validation dataset versus 0.804 for the APACHE II LR model. For the SAPS II score the LR model was only slightly better than the IBR estimator (AUC 0.867 vs. 0.877, differences have not been tested for significance). The performance of the SAPS II LR model could not be improved by any IBR estimator, whereas the APACHE II LR model was outperformed by some IBR estimators, e.g., adding diagnostic information to the APACHE II score yielded an AUC of 0.829 (versus 0.804 for the LR model). This is partly explained by the fact that for the SAPS II model the variable selection was based on statistical analysis and for the APACHE II model on expert consensus.

Conclusion: Instance-based reasoning can be a good alternative to the logistic regression model in scoring-based prognosis.

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DETECTION OF VENTILATION BY ELECTRICAL IMPEDANCE TOMOGRAPHY DURING LAPAROSCOPIC CHOLECYSTECTOMY IN OBESE AND NON-OBESE PATIENTS

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Introduction: General anaesthesia during laparoscopic interventions can lead to haemodynamic, metabolic and respiratory changes in obese patients [1]. With the help of electrical impedance tomography (EIT) the extent and the distribution of ventilated and non-ventilated lung areas can be represented [2]. The aim of EIT is to exploit the differences in the passive electrical properties of tissues. The method is able to generate a tomographic image by reconstruction of the internal conductivity distribution of the thorax by electrical measurements made at its surface (Figures 1 and 2). A goal of this clinical investigation was to examine the regional distribution of ventilation in obese and non-obese patients undergoing laparoscopic cholecystectomy.

Methods: After approval of the local ethics committee and a written declaration of informed consent 6 patients (ASA I/II; 3 obese [BMI(M) 35], 3 non-obese patients [BMI(M) 24]) scheduled to undergo elective laparoscopic cholecystectomy were enclosed into the investigation. After induction of general anaesthesia the patients were ventilated

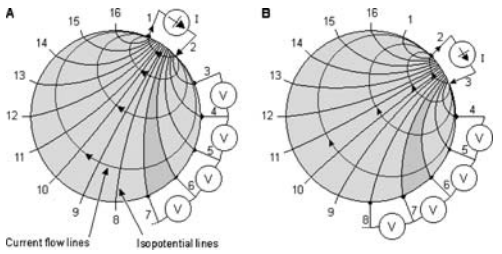

Fig. 1. Method of impedance data registration.

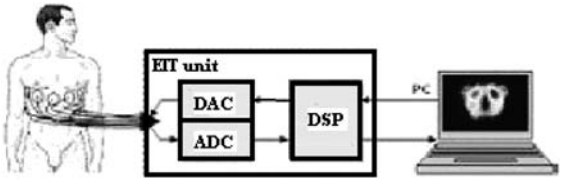

Fig. 2. Signal cascade during EIT measurements (DAC, DA-changer; ADC, AD-changer; DSP, digital signal processor.)

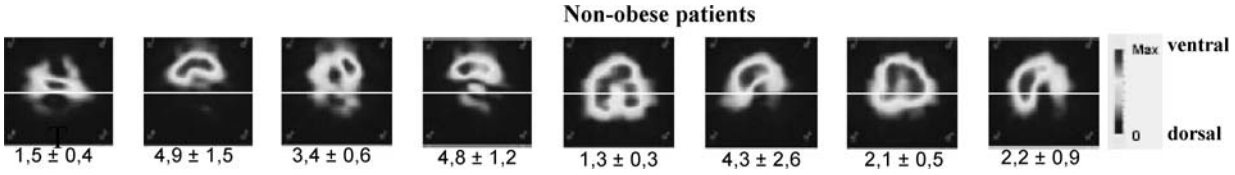

Fig. 3. Cross-sectional EIT images in obese and non-obese patients. IR (M ± SD); Obesity (n = 3)/Non-obbsity (n = 3).

in a volume-controlled mode (PRIMUS®, Dräger Medical, Lübeck, Germany). Standard monitoring was completed by invasive measurements of artery pressure, pulmonary compliance and arterial blood gases. EIT scannings (DRÄGER EIT Evaluation Kit) were performed before anaesthesia (T0), after induction of anaesthesia (T1), after insufflation (T2) and after exsufflation of CO_2 from the peritoneal cavity (T3). By the use of impedance ratio (IR), defined as the ventilation-induced impedance changes (VIC) of the nondependent part of the lung divided by the impedance changes of the dependent part of the lung, the distribution of ventilation in both parts of the lung were compared [3].

Results: After induction of anaesthesia the EIT showed a reduction of ventilation in the dependent lung sections. This effect was larger in obese patients. The induction of the carbon dioxide pneumoperitoneum (PP) leads to a stronger reduction of ventilation in the dependent lung areas in obese patients. After exsufflation of the PP the distribution of ventilation was comparable to those before PP. The changes of compliance, plateau pressure and $etCO_2$ corresponded to the expected alterations during laparoscopic surgery in obesity and non-obesity (Figure 3).

Conclusions: This new imaging technique is able to evaluate the topographical distribution of inspired air in mechanically ventilated patients. EIT can be used to detect regional changes in the distribution of ventilation and to monitor local effects of artificial ventilation influenced by body conditions (e.g. obesity, non-obesity) or the performed therapeutic procedure (e.g. pneumoperitoneum). It could be shown that obesity in comparison to non-obesity leads to a more inhomogenous distribution of ventilation.

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