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**Part 1 Free Papers**
**Part 2 Invited Lectures**

# Free Papers

## Evaluating the usability of data management systems for the OR

**Backhaus C, Marsolek I, Köth H, Friesdorf W, Okamura A***

Department for Human Factors Engineering and Ergonomics, Technical University of Berlin, Germany; *Department of Anesthesia, Hokkaido University Hospital Sapporo, Japan

**Introduction.** Deciding which data management system to buy for an OR requires a very profound information basis. Not only the costs of purchasing and introducing such a new technology but also reliable information about its process support and usability have to be considered as early as possible [1]. Therefore the assessment of those attributes is gaining more and more importance also for data management systems for the OR.

**Methods.** From the ergonomic point of view only a prior specification of the required process support can be the basis for a reliable usability assessment. In this context a participatory process flow analysis is used for the visualization of the momentary process flow together with potential users of the new technology. Afterwards all process modules are identified, that have to be optimized by the new technology and therefore define the systems' requirements. The usability of different technological solutions is then evaluated in a simulated clinical environment. For those process modules all interactions with the different technological solutions are identified and a specific number of potential users (e.g. anesthesiologists) fulfill their typical clinical tasks using the different systems. At the same time a group of usability experts assesses the different systems usability for all interactions separately either as "acceptable", "critical" or "unacceptable". Testing each system first without any additional instructions and then explaining the system's critical interactions also allows a later conclusion about each system's instruction requirements [2]. Additionally all users assess the system's usability using the following grades: very good, good, satisfactory, fair or poor.

**Results.** Using this procedure for the "anaesthesia induction phase" as an example for other clinical work flows the following results were achieved: All together 23 different process modules were identified. While 9 process modules showed a considerable potential for a process optimization by introducing a data management system, only 5 of them defined the most essential requirements for the new technology. The evaluation of a specific data management system showed that within those 5 process modules only 21 interactions had an "acceptable" usability without any additional instructions, but 12 interactions were "critical" and 2 even "unacceptable". After an additional instruction concerning the systems critical interactions all together 29 interactions had an "acceptable" usability and only 2 interactions remained as "critical" while no interaction was "unacceptable" anymore. In addition to that 7 potential users assessed the system's usability as good or satisfactory while only 3 assessed the system's usability as fair or even poor after testing the system.

**Conclusion.** The result of this exemplary study shows clearly, that for the tested system the required usability can only be achieved by an additional instruction phase concerning its critical interactions, which are a direct result of the usability study as well. Therefore using this procedure also for other technological solutions should not only result in a reliable usability comparison of different systems for specific process modules but also in an iterative optimization of the systems themselves as well as their instructions for critical interactions.

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## A new method for the identification of endotracheal tube position

**Zhou DC, Pan WJ***

Department of Anaesthesiology, Sir Run Run Shaw Hospital; *Department of Biomedical Engineering, Zhejiang University, Hangzhou, P.R. China

**Introduction**. Improper placement of endotracheal tube, such as oesophageal intubation, remains serious avoidable incidence. An endotracheal tube position detect system was designed with a magnet stylet and a magnetic field strength detector using Hall-effect sensor.

**Methods**. Hall-effect sensor is sensitive to magnetic flux density. It provides a voltage output proportional to the applied magnetic field. The magnetic field strength of a cylindrical magnet in its axle direction is related to the distance. When the output voltage of the sensor is detected, the distance between the sensor and the magnet can be calculated. In the detector, two Hall-effect sensors A3515 (Allegro Microsystems Inc.) with the differential input mode were designed to minimise the noise of earth magnetic field strength. An A/D converter worked at a frequency of 10 Hz. A micro controller (MSP430F1121, Texas Instruments Ltd.) processed the digital signal, and the result was displayed on the Liquid Crystal Screen (LCD) in millimeter. The magnet on a copper stylet was made of Rubidium-Ferrum-Boro sized 5mm (height) x 3.0 mm (diameter). *Laboratory test***:** Slowly move the magnet near to the Hall-effect sensor, the output of the detector was compared to a ruler. Clinical evaluation (1): 21 adult patients undergoing anaesthesia were performed endotracheal intubation and 12 of them were carried out intentional esophageal intubation immediately after endotracheal intubation. The Hall-effect sensor was fixed on the skin over the cricothyroid membrane before intubation and the magnet stylet in the tube. The distances detected during tracheal intubation and oesophageal intubation were compared. Clinical evaluation (2): A buzzer alarm of the detector was to be triggered when the distance detected was less than 35mm, indicating successful endotracheal intubation. The accuracy and time needed to identify tube position were evaluated in 30 cases.

**Results**. The result of laboratory evaluation showed less than 5% error in the range of 10mm to 50mm and was repeatable. In clinical evaluation (1), the minimal distance detected during tracheal intubation (25mm to 32mm) was significantly less than that of oesophageal intubation (31mm to 41mm). Identification of oesophageal intubations by distance from the tube tip to the skin over the cricothyroid membrane seems possible in most cases. In clinical evaluation (2), 23 cases were successfully intubated with the first attempt; alarm was triggered immediately. In the other 7 cases, intubations were not successful in the first attempt and no alarm was triggered, readjust were made immediately and alarms were triggered after successful intubation. Re-oxygenation with mask ventilation was not needed for all cases.

**Conclusions**. The conventional method of auscultation breathing sound needs connect the tube to the anaesthesia machine and ventilate to the tube. That needs more time and may causes inflation of the stomach in case of oesophageal intubation. The new detecting system recognises tube position quicker. For maximal patient safety, other method for tube position verification should be applied simultaneously.

# The Radiometer IT solution for the blood gas laboratory

**Kjøller K**

IT Business Development, Radiometer Medical A/S

Radiometer has a long history of providing blood gas solutions for hospitals. Our ABL blood gas analyzers are placed in laboratories and at decentralized locations. Radiometer products have always been known as high quality products and, functionality-wise, meet the requirements from our customers. There is a constantly increasing demand for integrating IT into the laboratory equipment. The IT solutions offered by Radiometer are state-of-the-art in respect of interfacing capabilities and instrument control.

This presentation will demonstrate some of the capabilities offered by our main products:

- ABL77 and the ABL700 Series of analyzer
- RADIANCE Stat Management System

Our products can be connected to the hospital network utilizing the TCP/IP protocol for communication between analyzers and hospital IT systems or for communication between the analyzers and the STAT Management System.

**General Interfacing Capabilities** – the Radiometer product provides a high degree of flexibility when interfacing to hospital IT systems. All products offer network and serial communication providing high-level ASTM and HL7 based communication. Radiometer has been heavily involved in the Connectivity Industry Consortium, which has provided the POCT1-A NCCLS standard for interfacing Point-of-Care equipment and data management systems to HIS/LIS systems. These standards are soon to be integrated into the Radiometer products for further flexibility.

**Master Patient Index lookup** – allows operators to download patient demographics to the analyzer during the analysis process. Based on the patient id. or accession number a query is sent from the analyzer to the Master Patient Index and patient demographics are automatically updated on the analyzer id. screen. Implementing this feature in a hospital reduces the risk of sample mix-up and ensures 100% data capture.

**Patient by Department lookup** – is normally used in remote units where samples are handled without, or with little, identification. The analyzer operator simply selects the right patient from a list of patients associated with the actual department. The list of patients is downloaded and maintained directly from the Master Patient Index.

**Remote Instrument Control** – the RADIANCE Stat Management system offers a unique solution for monitoring and support of remotely placed instruments. Real-time instrument status is displayed and analyzers can be supported in an efficient way to secure maximum performance. Implementing the RADIANCE Stat Management System together with the Radiometer ABL blood gas analyzers provides a cost effective solution that meets your QA requirements – all by the use of IT.

# Accuracy of noninvasive continuous blood pressure; measurement utilising the pulse transit time

**Lutter N, Kozma E, Stork W**

Department of Anesthesiology, University of Erlangen-Nuremberg, Erlangen, Germany; *Department of Information Processing, University of Karlsruhe, Karlsruhe, Germany

**Introduction**. As arterial blood pressure (BP) is linearly correlated to the pulse transit time (PTT) and thus to the pulse wave velocity (PWV) (1), BP can be calculated noninvasively and continuously by determining either PWV or PTT (2). However, this technology generates arbitrary units and therefore calibration is mandatory. The goal of this study was to quantify the agreement between invasive and noninvasive BP over time utilising laser Doppler flowmetry and plethysmography as a prerequisite of calibration.

**Methods.** After IRB approval and informed consent, 11 patients (ASA physical status II-IV) after abdominal surgery were included into this study. A prototype sampled, processed and visualised the laser Doppler flow (LDF), the plethysmogram (Pleth, Nellcor N-395), the ECG (Einthoven I), and the referential arterial BP of the contralateral radial artery (BD PMSET 1DT-XX). The oximeter probe resp. the laser Doppler flow probe consisting of a laser diode (837 nm) and a photodiode detector were placed at the index finger. PTT and PWV were then calculated quasi-continuously by means of the time interval between the ECG's R-wave and the maximum inclination of the LDF or the pulse oximeter's pleth signal, respectively. A major systolic and/or diastolic BP change exceeding the baseline by >20 % provided for the calibration period of the noninvasive configuration.

**Results.** During the calibration period noninvasive beat-to-beat blood pressure and referential arterial pressure yield correlation coefficients (R) of $R_{LDF}$=0.95 and $R_{Pleth}$=0.91 for $P_{sys}$, and $R_{LDF}$=0.85 and $R_{Pleth}$=0.84 for $P_{dia}$ but decrease significantly during the measuring period (>60 Min) immediately following calibration. Student's testing proves a significant difference between corresponding Rs (Tab. 1, $^{*}P<0.01$) and standard deviations (SD). Bland-Altman testing (calibration vs. measuring period) returns significantly differing SDs (calibration period ±4.62 mmHg vs. measuring period ±7.13 mmHg.

| ***Tab 1*** | $R_{LDF}^{*}$ Calibration period | $R_{Pleth}^{*}$ Calibration period | $R_{LDF}^{*}$ Measuring period | $R_{Pleth}^{*}$ Measuring period |
|---|---|---|---|---|
| $P_{sys}$ | 0.95 | 0.91 | 0.80 | 0.74 |
| $P_{dia}$ | 0.85 | 0.84 | 0.59 | 0.61 |

**Table 1**: Correlation coefficients of calibration and measuring period ($P^{*}<0.01$)

**Conclusions.** Both techniques agree statistically in providing for an accurate blood pressure indication during calibration but a significant drift is found when compared to the subsequent measuring period. Drifting of the arterial reference, physiological components not yet incorporated into the algorithm, and the prototype's instrumental stability may variably contribute to the decreased short-term performance of the noninvasive arrangement and therefore require further study.

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# Effects of profound hypothermia on EEG variables

**Doi M[1], Morita K[2], Sato S, Mantzaridis H[3], Kenny G[3]**

[1]Department of Anesthesiology and Intensive Care, [2]Surgical Center, Hamamatsu University School of Medicine, Hamamatsu, Japan; [3]University Department of Anaesthesia, Royal Infirmary, Glasgow, Scotland

**Introduction**. Temperature dependent effects must be defined when EEG variables are monitored intraoperatively during hypothermia. Our previous study of moderate hypothermia (minimum temperature 27 C), reported that the auditory evoked potential index (AEPex) was more stable and reliable than other EEG variables, and values of the bispectral index (BIS) were very variable [1]. The present study examined effects of profound hypothermia on AEPex, 95% spectral edge frequency (SEF) and BIS.

**Methods**. After obtaining hospital Ethics Committee approval and informed consent, we studied 10 patients undergoing aortic arch replacement under general anaesthesia with cardiopulmonary bypass (CPB). Anaesthesia was induced and maintained with propofol and fentanyl. Rectal and tympanic temperatures were monitored. Using CPB, profound hypothermia was achieved with a minimum rectal temperature of 22 C. BIS and SEF were measured using an EEG monitor (A-1000, Aspect Medical Systems). AEPex was obtained using a similar system to that in our previous study [2]. Each variable was recorded simultaneously and values averaged over 15 sec intervals.

**Results**. Mean minimum rectal and tympanic temperatures were 21.7 and 16.5 C, respectively. During the cooling phase, median values of AEPex, SEF and BIS slightly decreased with decreasing rectal temperature (Figs 1-3). Values of AEPex were tightly distributed between 35 and 22 C. Values of SEF were widely spread below 25 C. The values of BIS showed remarkable changes depending rectal temperature with large inter-patient variability (Fig 4). One patient described with closed circles had high BIS values even during profound hypothermia. Other nine cases showed biphasic changes of BIS values with the minimum value of 0 during hypothermia. Mean elapsed time from the BIS value of 0 to the minimum rectal temperature was 15 min.

**Conclusions**. The AEPex was the most stable among three variables and the BIS showed large variability among the patients during profound hypothermia.

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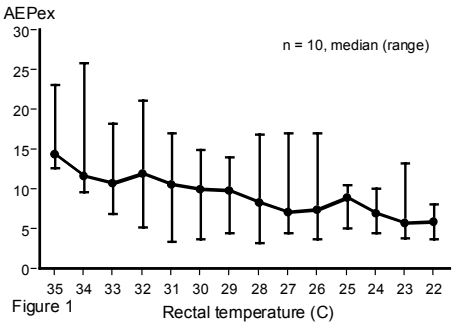

Figure 1

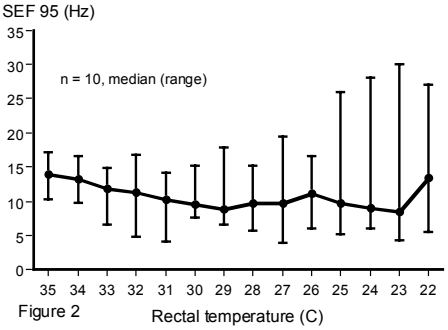

Figure 2

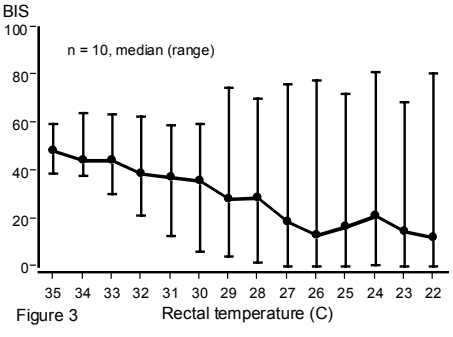

Figure 3

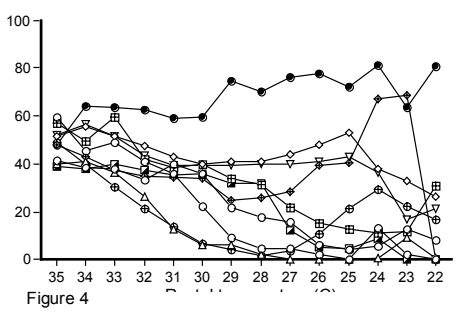

Figure 4

## The virtual medicine platform Zürich: One year of online experience

**Langedijk A, Haller U***

ICT coordinator, *President of the Didactics Committee, Faculty of Medicine, Zurich University, Zurich, Switzerland

In 1999 the Swiss federal state started the "Swiss Virtual Campus" initiative (SVC)[1]. At the same time the University of Zurich founded the ICT competence centre[2]. Both organisations stimulate e-learning projects, either on a state-level (SVC projects are always a cooperation between at least three universities) or at local level. The Medical Faculty of the University of Zurich participates in 21 funded e-learning Projects (status September 2002).

One third of the medical e-learning projects in Zurich joined forces and decided to cooperate in the "Virtuelle Ausbildungsplattform Medizin" (VAM). The independent projects are part of the VAM meta-level and are assessable via the common portal site[3]. The e-learning modules contain pre-clinical topics like anatomy, histology and biochemistry, and clinical topics like differential diagnosis, gynaecology and paediatrics. The meta-level offers general functionalities like search and glossary, as well as the VAM community. In this online community elaborate communication channels between teachers and students and between students themselves are implemented. Since October 2001 more than 2,500 medical students in Zurich can study online. During a two-year pilot phase, the current e-learning projects should show their best integration and complementary value to the traditional classroom teaching.

In this presentation we show highlights from different subjects, in which new media and new technologies are used for new didactical concepts. With the help of examples is shown how e-learning can be used in the teaching practice. Finally we will give our perspective on the strategy for the necessary future e-learning infrastructure.

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## Pulse oximetry artifact recognition algorithm for computerised anaesthetic records

**Gostt R, Rathbone G, Tucker A***

La Trobe University, Department of Electronic Engineering, Bundoora, Victoria, Australia; *Monash Medical Centre, Department of Anaesthesia, Clayton, Victoria, Australia.

**Introduction**. Computerised anaesthesia record keeping systems download physiological data directly from the patient monitoring equipment recording both genuine and artifactual data indiscriminately on the anaesthetic record. Artifactual data is not representative of the patient's true condition making retrospective analysis of the record difficult, with associated medico legal implications. This study developed an automatic artifact recognition algorithm and sought to evaluate the algorithm's accuracy in routine surgical procedures.

**Methods.** A semi-automatic anaesthetic record keeping system called MacAnaesthetist was developed for the Apple Macintosh computer incorporating an algorithm to automatically recognize pulse oximetry artifacts. Artifactual oxygen desaturations < 90% were annotated on the anaesthetic record in real-time by analyzing physiological data from a Datex AS/3 Anaesthesia Monitor. Accuracy of the artifact recognition algorithm was determined by conducting an

observational study during routine surgical procedures (N=20). For each procedure one anaesthetic record was made by an anaesthetist using the Datex AS/3 record keeper, while a second anaesthetic record was produced in parallel using MacAnaesthetist. A copy of each Datex AS/3 record was kept for later review by a group of anaesthetists (N=20), who judged oxygen desaturations < 90% to be either genuine or artifact.

**Results.** The 20 anaesthetic records collected during the clinical trial contained 13 oxygen desaturations < 90% - 9 artifactual and 4 genuine. MacAnaesthetist correctly categorized 8 out of 9 artifacts and 4 out of 4 genuine oxygen desaturations, resulting in a specificity of 100%, a sensitivity of 88.9% and an overall accuracy of 92.3%. A post operative review of the Datex AS/3 Anaesthetic Records (N=8) by 20 anaesthetists resulted in 127 correct responses out of total of 200. The remaining Datex AS/3 records (N=12) were excluded from review since they did not contain any oxygen saturation values < 90%. Anaesthetists gave 50 out of 60 correct responses when identifying genuine oxygen desaturations and 70 out of 140 correct responses when identifying artifacts. This resulted in a specificity of 83.3%, a sensitivity of 55% and an overall accuracy of 63.5%. Accuracy of individual anaesthetists varied between 40% and 90%. For two specific instances of oxygen desaturations < 90%, accuracy of the clinicians varied from 0-100%. In one instance all anaesthetists correctly judged a true oxygen saturation < 90% to be a genuine desaturation, but in another instance all 20 anaesthetists incorrectly judged an artifactual oxygen saturation < 90% to be genuine.

**Conclusions.** The artifact recognition algorithm developed in this study was more accurate than anaesthetists who postoperatively reviewed records produced by an existing computerised anaesthesia record keeping system. Artifact recognition algorithms have the potential to recognise artifacts with greater accuracy, assisting clinicians to more correctly interpret abnormal data when reviewing computerised anaesthetic records. Further research is required to develop artifact recognition algorithms for other physiological parameters.

## Development of a semi-automatic medical report

**Röhrig R, Kiefer B*, Demming R*, Michel A, Benson A, Hempelmann G**

Department of Anaesthesiology, Intensive Care Medicine and Pain Management, *Department for Klinical and Administrative Data Processing, University of Giessen, Germany

**Introduction.** Since 1999, the medical documentation of the surgical Intensive Care Unit has been conducted with the Patient Data Management System (PDMS) ICUData (IMESO, Germany) [1; 2]. Medical reports were created with a commercial word-processing software. The medical staff felt the need for a word-processing software which supports a semi-automatic creation of medical reports as well as the integration of the documents into the electronic patient record.

**Methods.** In co-operation with the company IMESO, a word-processing software was developed, using the programming language Microsoft Visual C++. This software has several functions. One centrepiece of the project was the development of a parser which, with information from the clinical database of the PDMS, can translate context-sensitive text elements into a comprehensible, gender-specific text. The documents are entered into the database of the PDMS via a Health Level 7 protocol. For this, the document structure is sent in XML format, and the text elements are sent in rich text format (RTF) as OBX segments. In order to simplify the creation of medical reports even further, the option to create standard templates was incorporated. Templates are created in an administrator mode from within the application. The administrator can choose from which of the text elements a summary is automatically created. This summary can be read in the tool tip of the patient record.

**Results.** Following a test phase, the system was implemented in the Intensive Care Unit with document types for medial report creation and for consultations in January 2002. Because of the stringent user menu prompts, little time needed to be expended for user training. Until 1st of August 2002, a total of 2049 documents, of which 1238 were medical reports and 811 consultations, were created on the Intensive Care Unit. With the integration of the documents into the database, the information contained on the documents is available with the same functionality (user interface layout, search, etc.) as all other medical information in the graphical-user-interface of the electronic patient record of the PDMS. With the standard texts and the context-sensitive text elements, considerable savings in time and effort were achieved.

**Conclusion.** The newly developed program supports the daily work of the medical staff with the integration into the electronic patient record and the context-sensitive text elements. The main focus of further development will be on a continuous expansion of the parser and on the implementation of the new HL7 Clinical Document Architecture (CDA) for data exchange with external systems [3].

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## Computerized recording of a prospective clinical study: comparison of blood loss during general and spinal anaesthesia in total hip replacement


**Hartmann B, Junger A, Benson M, Lorson S, Jost A, Hempelmann G**

Department of Anesthesiology, Intensive Care Medicine, and Pain Management, University Hospital Giessen, Germany


**Introduction.** Complete data recording is one of the key requirement of anesthesia information management systems (AIMS) being a prerequisite for subsequent scientific evaluation and quality assurance. We designed a prospective study to utilize the resources of our AIMS to assess differences in blood loss during general (GA) and spinal anesthesia (SA) in total hip replacement using flow cytometry (1;2).

**Methods.** In this study we used the anesthesia record-keeping system NarkoData Version 4 (Imeso GmbH, Hüttenberg, Germany) (3) for collection of all perioperative data. Standardized electronic anesthesia record charts were configured for the two types of anesthesia according to the study protocol (standard charts "general anesthesia" and "spinal anesthesia"), thus assuring a high uniform quality of data of all required perioperative variables. Vital parameters were automatically recorded via an RS232 interface of the patient's monitor. Results of blood gas analysis were imported directly from the analyzer into the anesthesia records; results of flow cytometry used for intraoperative blood loss determination were imported electronically from the device into the database of the AIMS. For statistical evaluation, data were exported from the database into the SPSS statistics program (SPSS® GmbH Software, Munich, Germany) using a standard SQL-tool.

**Results.** Time needed for configuration of the electronic standard charts was approximately four hours. Data of all 42 patients (18 GA, 24 SA) have been evaluated. There were no missings concerning the patient's biometric data, laboratory parameters and surgery times. The study

revealed no significant differences ($p<0.05$) between the groups in intraoperative blood loss (GA 1,688±921ml, SA 1,581±1,052ml), mean body temperature (GA 35.5±0.5°C, SA 35.6±0.4°C), mean arterial blood pressure (GA 90±7mmHg, SA 89±9mmHg) and duration of surgery (GA 125±46min, SA 120±40min).

**Conclusion.** The controversial discussed influence of anesthesia technique on intraoperative blood loss in total hip replacement could not be confirmed by this study. The AIMS configured to study requirements was suitable to support data recording in a prospective clinical study avoiding human errors and "smoothing effects" (4-6). Whether the means of recording influence data quality in prospective studies and subsequently the study results has yet to be investigated.

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## Structure of a computer-aided DRG quality-management with a patient data management system


**Banzhaf A, Röhrig R, Quinzio L, Hartmann B, Michel-Backofen A*, Hempelmann G**

Department of Anesthesiology, Intensive Care Medicine, and Pain Management; *Department of Medical and Administrative Data Processing, University Hospital Giessen,Germany


**Introduction**. With the implementation of DRG (diagnoses related groups) as a calculatory basis for financial assessment the quality of coding of both diagnosis and procedure becomes economically crucial [1, 2]. Designing a workflow for a DRG-based coding was the target of this study.

**Methods**. The coding software Diacos (ID, Germany) has been integrated into the administration of diagnoses and procedures of the Patient-Data-Management-System (PDMS) ICUData (IMESO, Germany) [3, 4] and a HL7-connection to the Clinic-Information-System (CIS) Orbis (GWI, Germany) has been installed. Diagnoses are entered in coded format. The code can now be used for different features such as doctor letters. Quality checks (on levels of unit, department, administration) and tests concerning the quality of coding have been carried out and a reporting and feedback system has been established to support the users.

**Results**. During the first six months of 2002 a number of 3,818 diagnoses from 785 patient stays have been coded at the intensive care unit (an average of 4.86 diagnoses per stay). Diagnose and DRG-related analysis have been made available through PDMS (decoding of the coded diagnoses sorted by time period, content and frequency). Quality checks and regular feedback increased the number of coded diagnoses and led to less unspecific codings. The relation between main and side diagnoses mirrors the patient collective on the intensive care unit, the fraction of relevant side diagnoses corresponded the standard [5].

**Conclusion**. The implementation of DRG-adequate coding is accompanied by a considerable effort in the fields of employee training, controlling and IT administration. To support the coding doctor a further optimization of the software providing special functions such as controlling,

completeness and plausibility checks (when moving patients to other units) and automatic interpretation of documented data is recommended.

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## How to make users´ knowledge fruitful for evaluation and design processes


**Bönisch B, Held J**

Swiss Federal Institute of Technology Zurich, Switzerland


**Introduction.** Designing for the complex system of anaesthesia is a difficult task. User orientation can be improved by application of prototyping and usability-tests. But what about analysing users´ needs independently of perceived design solutions - is it helpful?

**Method.** Nineteen user-interviews (obtained from 7 anaesthesia medical doctors and 12 nurses) were conducted in different types of Swiss hospitals (university, public and private) using a specially designed interview-technique: object-based and containing interviewee-action: In the first part the interviewee could browse through thirty different types of common respirators (results of a market research) and give narrative statements concerning pros and cons of their interfaces. The second part was dedicated to autonomic interface design using the “Valamo”-Variable Layout Model, which consists of magnetic objects representing different solutions for anaesthesiological display-information-parts and input devices. Duration for both parts was between 45 and 80 minutes. The interview-sessions were videotaped and recordings were transcripted afterwards. Results combined with ergonomic design principles [1-4] were implemented in a first interface-simulation. This basis was processed during 14 iterative loops of a human centred design circle [5] in co-operation with experts of anaesthesia and ergonomics.

**Results.** The interviewees had the following experience:

- on the job: median: 6 years, 7 persons had under 2 years, 8 persons had between 10 and 25 years
- with respirators: mean: 6 different types

Forty keywords were used to structure about thousand user-statements in a database. The expressed needs and wishes were sorted into two mind-maps with about 100 elements each. Concrete comments about pros and cons of the thirty different respirators were collected according to each. Summarising users´ needs showed strong adaptation to the interfaces they are using. The requirements and wishes determined were inconvergent and contradictory in many aspects. The

redesign-loops led to a new interface-solution. From the experiences gained through this process design-recommendations for respirator-interfaces will be drawn.

**Conclusions.** Adaptation to the mainly used respirator type proved stronger than expected, whereas redesign-loops showed that users are open for and willing to try out new solutions altogether. The common procedure of starting with designing and afterwards testing leads to insufficient solutions if applied to complex systems. Investigating users´ needs may seem to bring inconsistent results, a difficult basis to develop new design. Nonetheless it may turn helpful by showing sensible areas where to spend more attention to. The benefit lies within a learning process, possibly unconscious and inconcrete, but necessary for understanding the system. In this case, solutions for most of the contradictory wishes could be found.

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## Encoded alarms in anaesthesiology


**Le Feber J, Eikelboom A**

University of Groningen, the Netherlands


**Introduction.** A recent questionnaire revealed that auditory alarms in anaesthesia are not always recognized easily and that more information in the alarm would be appreciated. We concentrated on ergonomics and designed alarms that encode the urgency of a problem, the apparatus that gives the alarm and the actual problem.

**Method.** We designed a computer program that generated alarms from a scenario file. Alarms were generated in either control mode or encoded mode. In control mode each alarm consisted of a beep and a message displayed on the screen. This message contained information about the urgency and a description of the problem. In encoded mode the urgency of a problem, the apparatus that gave the alarm and the actual problem were encrypted in the alarms. Four urgency levels were distinguished and indicated in the alarms (see Table 1). Each apparatus was encoded by an associative auditory icon The actual problem was shown as a short message on the screen. In very urgent situations, one or two audible keywords were added.

| Urgency level | Alarm |
|---|---|
| 1. life threatening situation | Siren + auditory icon + audible text + visual text |
| 2. a problem not very acute | Auditory icon + visual text |
| 3. technical failure | Visual text |
| 4. unknown urgency | Auditory icon + visual text + '?' icon |

Table 1. Urgency levels and the corresponding encoded alarms

Eight volunteers were given a task on the computer and were asked to respond to the generated alarms. Their goal was to turn off urgent alarms as quickly as possible. To do so they first had to select an apparatus from a list. Then a new list appeared with possible reasons for alarms (possible problems) on this apparatus. The alarm was turned off when apparatus and problem were correct. The success of the encoded alarms was assessed by average reaction times (the time needed to

turn off the alarm) and average number of errors. There were two possible errors: selection of a wrong apparatus (apparatus errors) or a wrong problem (problem errors).

**Results.** In encoded mode the average number of problem errors was significantly lower than in control mode (0.2 vs 0.4. t-test: $p<0.04$). The average number of apparatus errors tended to be lower as well (0.4 vs 0.6). This difference, however, was not significant. The encoded alarms had the same average reaction time as the control alarms (25±22 and 25 ±27 s, respectively). In contrast to control mode, however, encoded mode showed significantly shorter reaction times for alarms with high urgency (ANOVA, $p<0.001$). Several times alarms occurred simultaneously (control mode:12, encoded mode:16). The most urgent alarm was turned off first in 33% and 88%, respectively.

**Conclusion.** Encoding priority in alarms seems to work properly, urgent alarms are responded to faster. Furthermore, if two or more alarms coincide, high priority alarms are usually identified and turned off first. In both modes capnogram and ventilator were interchanged quite frequently (control mode: 63%, encoded mode: 60%). Encoded mode showed no improvement, probably because both auditory icons were too similar. In the rest of the group the average number of apparatus errors was significantly reduced from 0.6 to 0.3. The ability to encode urgency, apparatus and problem in alarms means that it will be very useful to develop artificially intelligent systems that can indicate these factors. Together with encoded alarms they may result in shorter reaction times and less errors.

## Web-cam contributes to surgery management in operating rooms

**Morita K, Sanjo Y, Yokoyama T**

Surgical Center, Hospital of Hamamatsu University, Hamamatsu University School of Medicine, Handayama, Hamamatsu, Shizuoka, Japan

**Introduction**. The management of surgery, such as dispatching control of scheduled or on-call surgeries, upgrading the economic balance with increasing number of cases per day while no increase of human or machine resources, and providing their safety on the patients under surgeries. A video system is considered as a powerful helper for this purpose. Recently, many web-cam systems can be seen at many places in the town, city widely in the world. Our objective is whether the web-cam system can be effectively usable as the video monitoring system in operating rooms.

**Methods**. Six web-cams were installed in 5 operating rooms, one by one, and 1 at the central utility space in our surgical center. One web-cam consists a set of one pan, tilt and zoom capable video camera (Canon VC-C3) for capturing video images and a web server (Canon VB-100) for distributing the movie and still images to the client via the internet. A home page application was programmed by the HTML and placed at the web server and providing multi-room video views in single window or one enlarged view in single window selectively. After 3 months later of completing the introduction of that system, a questionnaire, which subjected to 4 senior managing nurses, was carried out for surveying its performance. The answer to each item in questionnaire was scored proportionally in percent scale of maximum satisfaction as to be 100%.

| QUESTIONNAIRE ITEMS | SCORE (%) |
|---|---|
| **In-room management** | |
| Identify patient come in | 100 |
| Identify start of induction | 96 |
| Identify end of induction | 86 |
| Identify start of surgery | 90 |
| Identify surgeon | 88 |
| Identify end of surgery | 92 |
| Identify patient awake | 88 |
| **On-call, emergency scheduling** | |
| Planning the start time | 82 |
| Staff allocation | 76 |
| **Workload management** | |
| Coffee, lunch break | 78 |
| Allocating substitute staff | 78 |

**Results**. A result of questionnaire survey was showed in right table.

**Conclusions**. The web-cam system which we had installed in our operating rooms was speculated as enough valuable for current our objective.

## First results of an international survey on the improvement of real time medical support systems

**Pott C, Le Feber J**

Department of Mathematics and Computing Science, University of Groningen, The Netherlands

**Introduction**. At the ESCTAIC meeting 2001 we introduced our project on requirements engineering in real time medical support systems [1] following the theory of Cognitive Work Analysis (CWA) [2]. Now we would like to present some results from our final questionnaire.

**Methods**. After OR observations, group discussions and a pre-test questionnaire in march 2002 we published our questionnaire at http://www.cs.rug.nl/anaesthesia-questionnaire. Our questionnaire consists of 105 questions mostly with answers on a 7 point Likert scale. Up to now our sample consists of 268 questionnaires from 29 different countries.

**Results**. Based on previous findings of CWA we theorised that not mainly the actual amount of information has to be improved but the way this information is presented. In line with this theorising our participants indicated an improvement in display ergonomics to be more important than improving the measurement technique. Actually, improvements in display ergonomics were rated to be most important and to be even more important than improving the alarm functions. Furthermore, within an open question we asked what else should be improved (besides the above mentioned items). Participants indicated a general improvement of communication to be very important. This includes the communication within the team, the communication be-twin devices ("spaghetti made by cables") and the communication via networks to databases, e.g. of stored patient data. Additionally, we asked which characteristics of communication with other experts during surgery are important. It turned out that an immediate response of the expert was perceived to be most important followed by an easy transfer of information. However, being able to indicate the urgency of the situation by transfer of emotions was rated as being much less important. Another issue was the relevance of a decision support systems (DSS). We asked our respondents to indicate the importance of nine potential different features of such a support system. A factor analysis of the results revealed only one factor with an Eigenvalue >1 (explaining 47.6% of the items' variance). Besides, this one-dimensionality of our results showed that the participants differed to a high degree in the importance they ascribed to the different features. Thus, whereas some Anaesthesiologists are extremely interested in DSS, others consistently indicated such a system to be disturbing.

**Conclusion**. Although the here introduced results cover only a small part of our questionnaire and our analyses so far are still preliminary, they strongly support our theoretical reasoning. Anaesthesiologists definitely want their monitoring devices to be improved. But in accordance to our assumptions there cannot be one single best solution to the requirements of all Anaesthesiologists. Quite to the contrary, each individual differs in his/her demands with regard to an ideal monitoring system. In developing the next version of our prototype we will consider the important findings.

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## Measuring patient satisfaction, quality of outcome, and economic benefits of regional anesthesia techniques in trauma and orthopedic surgery

**Bothner U, Wolfers C, Hirchenhain K, Bauer A, Eble T, Pittner T, Brinkmann A**

Department of Anesthesiology, University of Ulm, Germany

**Introduction.** The implementation of quality documentation systems and the provision of benchmark data have become an imperative task for anesthesia providers to measure their service processes. To yield maximum patient satisfaction and to guarantee high quality care with a minimum of costs should be the key to enduring success in an increasingly competitive health care market. This warrants continuing scientific efforts to develop robust methods for anesthesia outcome assessment.

**Methods.** Two domain specific questionnaire instruments as proposed by the Australian group of Myles et al. [1] and the German Society of Anesthesia and Intensive Care Medicine (DGAI) [2] were tested during a 6 month study period in 535 consecutive trauma and orthopedic surgery patients at our University teaching hospital. Residents and staff anesthetists were trained and supervised to provide standardized procedures of regional anesthesia (RA) with or without general anesthesia (GA). Patient risk factors, type of surgery, details of anesthesia technique and medication, as well as timestamps for each process step were recorded in an online database. Both questioners were applied postoperatively in the PACU, on the ward after one postoperative day, and mailed to all patients after discharge. Statistical comparisons were accomplished with multivariate regression methods.

**Results.** Pain, discomfort, other adverse events, and quality of recovery were significantly more favorable ($P<0.001$) in the RA groups. Most differences disappeared, however, after postoperative day one. RA offers distinct advantages in terms of resources consumed such as treatment time and medication. Overall patient satisfaction was rated good to excellent for all groups and all points in time. The study database provides more than 200 quality-oriented items per patient for comprehensive risk-adapted outcome analyses.

**Conclusion.** Myles' questionnaire was extensively validated and practically used in an English speaking culture only. The DGAI questionnaire was composed by an expert panel as part of the German Anesthesia Quality Assurance Project without methodological validation at this point. The question remains how they should be used in a specific point of care environment. Ceiling effects in the answer pattern were detectable for several items, especially for overall satisfaction, which limits their usability for routine evaluation. Summary constructs such as patient satisfaction or quality of recovery are not trivial to trace and discriminate between different anesthesia techniques, although sub-components may show clear differences. Both questioners provide a framework and starting point for postoperative anesthesia quality assessment. Local adaptation and validation is essential.

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# Determinants of alarm-rate and the potential of intelligent monitoring systems in routine anaesthesiological use

**Broscheit J, Lorenz KW, Baumeister J*, Tannert A, Greim CA**

Department of Anaesthesiology, University of Würzburg Hospitals, Germany; *Department of Artificial Intelligence and Applied Computer Science, University of Würzburg, Germany

**Background.** We investigated the determinants and the implications of alarms for the further development of a monitoring system augmented with artificial intelligence techniques assisting the anaesthesiologists.

**Methods.** We observed anaesthetists responses to intra-operative monitoring alarms during various surgery. Alarm limits and frequency of alarm reports were documented including the parameters heart rate, blood pressure (invasive and non-invasive), $SpO_2$, $etCO_2$, $FiO_2$, PAW. The alarms were evaluated in qualities assigned to: 1) artefact / being ignored as a nuisance alarm, 2) change noticed before alarm report / functioning as a reminder, 3) alarm without requiring therapeutic consequences / corrective response and 4) alarm requiring therapeutic consequences / corrective response. All patients risk score ASA I-III were included, introduction and emergence from anaesthesia were excluded. Alarm limits, alarm frequency, ASA risk-score, observation-time and alarm-quality were documented using a blinded questionnaire. We created a „norm adjusted alarm index" (Fig. 1) to compare the alarm rate settings. The alarm limits defined as normal for the development of the „norm adjusted alarm index" are listed in table 1.

**Results:** During 120 procedures with a complete operation time of 15640 minutes 237 alarms were observed. 130 (55 %) of these alarms were classified as quality 1 (artefact). 68 (52 %) of these artefacts were caused by pulse oximetry, followed by 46 (35 %) caused by ECG. Other parameters were negligible (1 to 5 %). Regression analysis (Fig. 2) of „norm adjusted alarm index" vs. alarm-frequency failed ($r = 0{,}113$; $p = 0{,}082$; "= 0,05).

**Conclusion:** The technical management of artefacts is still a major problem. Pulse oximetry in particular, followed by ECG, is a substantial reason for the appearance of artefacts. Actual or potential consequences of this research include the design of alarm systems that are more informative and more sensitive to operative context than current systems. On this basis a major goal would be the development of a computer system enhanced with artificial intelligence techniques for the identification of artefacts and the further detection of critical events. This might lead to an -expert-based knowledge system capable for on-line and real-time analysis of patient data during surgery reducing the frequency of alarms and supporting the anaesthesiologist during critical events.

**Appendix:**

$$\{(\text{alarm}_{\max} - \text{alarm}_{\min}\} / ) \text{ norm}\} - 1$$

**Fig. 1.** Formula of norm adjusted alarm index alarm max / alarm min are documented maximum and minimum alarm limits during study.

| | norm $_{max}$ | norm $_{min}$ | Δ norm |
|---|---|---|---|
| HR | 100 | 60 | 40 |
| BP | 140 | 80 | 60 |
| $SpO_2$ | 100 | 94 | 6 |
| $pCO_2$ | 100 | 30 | 70 |
| $FiO_2$ | 100 | 30 | 70 |
| PAW | 25 | 10 | 15 |

**Table 1.** Alarm limits defined as normal norm max/norm min are maximum and minimum alarm limits supposed as normal ranges; norm is the difference between these limits.

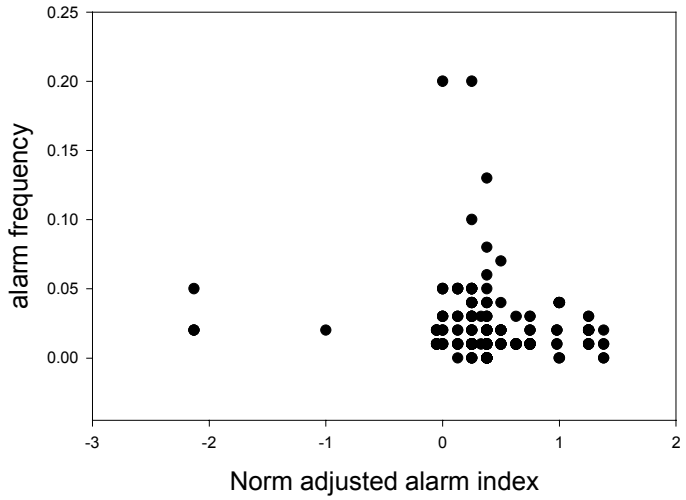


**Fig. 2.** Regression analysis, norm adjusted alarm index vs. alarm frequency by time.

## In vitro and in vivo evaluation of a novel drug delivery system for very low flow rates

**Kozma E, Richter M*, Wackerle M*, Lutter N**

Department of Anesthesiology, University of Erlangen-Nuremberg, Erlangen, Germany, *Fraunhofer Institute for Reliability and Microintegration, Munich, Germany

**Introduction**. In order to meet the requirements of drug and fluid administration at very low dosing rates even in the sub-µl-range a portable drug delivery system (MEDOS) was developed, mainly consisting of a pressure-generating unit and a high-precision flow resistor. Utilizing a prototype configuration this novel device was tested for dosing accuracy, safety, and ease of use and additionally evaluated along with postoperative pain therapy.

**Methods**. The drug reservoir (10 ml) conventionally pressurized by a spring actuator is connected to a disposable fluid connector carrying a silicon microchannel thereby providing for a linear correlation of reservoir pressure and flow. Moreover, the superior geometrical accuracy of the micromachining technology utilized to manufacture the microchannels allows for precisely adjustable flow rates: After defining the microchannels by lithography KOH wet etching is employed to structure the channel subsequent to extensive computer simulations of the mechanical and microfluidic properties required. Capillary flow rates of water were then studied by gravimetrical measurement. To appropriately administer drugs the viscosity of local anesthetics, analgesics etc. was determined experimentally. After IRB approval and informed consent we examined MEDOS in 39 adult patients after visceral surgery. All patients were randomized into

two groups receiving either S-ketamine 2.5% or NaCl 0.9% intravenously and continuously in addition to conventional PCA with morphine. The study protocol was focused on the performance of MEDOS including multiple visual and microscopical examination of any capillary we used and on drug consumption.

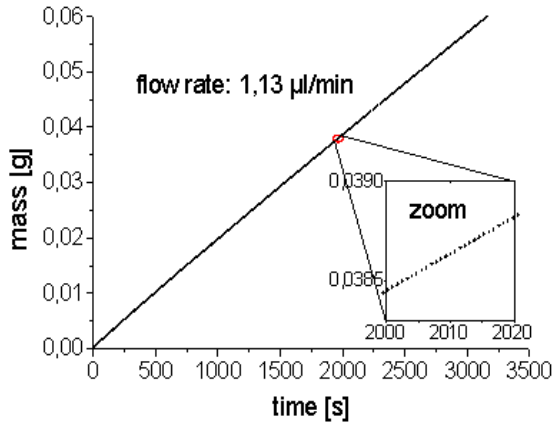


**Fig 1.** Flow rate of a silicon capillary (no 37) at 500 hPa. .and 22°C.

**Results**. Viscosity measurements of various drugs demonstrated a strong non-linear dependence on temperature, but differed from water by 4 to 15% between 20 and 50°C. Gravimetrical measurements of the capillary flow rate resulted in 1,12 ± 0,04µl/min (1*SD, *Fig 1*). As for the clinical trial we noted a median infusion rate of 93,7 ± 35,76µl/h for MEDOS comprising an overall measuring time of 1054.4 h. Visual examination of the 65 microrestrictions used revealed 32 suspected of malfunction, however, microscopical control confirmed only 20 (31%) as damaged. The S-ketamine group rated for a significantly lower morphine consumption when compared to the control group (0,023mg/h/kg vs. 0,031mg/h/kg; non-Gaussian distribution).

**Conclusions**. Its miniaturization potential and superior device-to-device reproducibility due to low-cost micromachining technology provide for a high *in vitro* accuracy of MEDOS at very low flow rates, however, the *in vivo* drug delivery differed from the predicted flow rate by 50% approximately. Inappropriate preparation of the drug delivery system, unintended manipulation of the fluid connector by the patient, and the difficult assessment of the delivered drug amount by determining the weight of MEDOS before and after therapeutic use variably contribute to the aforementioned dosing error. In analogy to other studies (1,2) addressing bolus injection of high S-ketamine-doses continuous low-dose infusion of S-ketamine (~37mg/24h) significantly reduced morphine consumption.

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# Invited Lectures

## Interfacing man and machine: a question of masters and slaves?

**Held J**

Institute of Hygiene and Applied Physiology, Swiss Federal Institute of Technology, Zurich, Switzerland

**Introduction.** The presentation addresses user-centred design issues related to man-machine interfaces in hospital environments. Interface design dictates human interaction and can influence and even alter the work environment in which they are being used. Nowadays, machine development is centred around data processing and information flow management. Consequently, such developments have changed the way humans conduct work; the impacts of which are difficult to grasp. The question now is whether computation takes command of our work? Discussing aspects of interface design will lead to a better understanding of this question.

**Methods.** Demonstration of man-machine interfaces and interactions to explain aspects of:

a) Ergonomic principles
b) User-orientation
c) Technology
d) Standardisation
e) Rationalisation

**Results**

a) There is a lack of applied ergonomics in some interface design. Very basic visual demands, for example the legibility and ergonomic requirements in dialogue design, usability or user guidance are disregarded – despite the established know-how.

b) "Usability Engineering" is implemented in design processes of some companies of medical devices to guarantee user-orientation.

c) A vast number of machine features and functions are mirrored in the interfaces. This is named at the user's site as illness of "featuritis". New interface technologies lead in the operation rooms to a situation comparable with the "glass cockpits" in aviation. Touch screen technology is providing design companies with versatility and cost reductions but need to adapt ergonomic design criteria.

d) Interface developments in the past and present show that some standardisation's "designed" the user skills in the way that the user learn a certain interaction behaviour which may built an hindrance for further interface changes.

e) By focusing on data management systems work rationalisation can cause erosion in process knowledge. Thus the easy management of a flood of data may lead to a lack of human-human interactions and a lack of impressions for the best data interpretation to reach the status of an information.

**Conclusions.** Ergonomics is regarded in the design process as static criteria's but seldom as a method. In addition usability engineering helps to bring in ergonomics as a process of user-orientation. But this has the nature of a feed back loop. Thus it has a corrective and often superficial effect on interface design and rarely leads to innovations. User knowledge transfers and work system analysis, i.e. work flows transparency can overcome this disadvantage. The need

therefore is urgent because of machine automation and the fact that than the interface design plays the major role in supporting the user with “Master” knowledge of the process.

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## Technology and performance of anaesthesia depth monitors

**Schraag S**

Department of Anaesthesiology, University of Ulm, Germany

**Why to monitor the central nervous system?**

Obviously, all of us have got along without any monitor until now, so why should we bother? The practice of anaesthesia remains one of the safest and most effective in medicine. Furthermore, like all new technologies, CNS monitoring devices will add something to the cost of delivering anaesthesia. On the other hand, there is no doubt, that significant unpredictability and uncertainty still exists in the delivery of anaesthetic drugs. This is reflected in the variety of suggested dosing regimens, especially when combining different anaesthetic agents. Some patients still suffer intra-operative awareness and may consecutively develop posttraumatic stress disorder [1], whereas others still have prolonged recovery due to relative overdosing even with otherwise short-acting drugs. However, the primary reason for using any monitor designed to reflect the anaesthetic state must be to improve patient care.

**What is the rationale of anaesthesia depth monitoring?**

Adequate oblivion is a requirement and expectation of patients undergoing general anaesthesia. The main target of drugs used in general anaesthesia is the central nervous system and therefore a reliable signal produced in the CNS is required, which reflects the balance of increasing concentrations of general anaesthetics on one hand and the CNS effect of nociceptive stimulation produced by surgery on the other [2]. In this sense, a monitor designed to measure depth of anaesthesia should be able not only to quantify the concentration-dependent effect of anaesthetics but also to detect an arousal situation based on an imbalance of the anaesthesia-stimulation relationship, which is dynamic over the range of surgical conditions and potentially dependent on the choice of anaesthetics used.

*How can we measure depth of anaesthesia?*

Over the last decade a variety of monitors that characterize the CNS under anaesthesia have been developed, refined and clinically evaluated. The latest developments include processed derivates from the electroencephalogram (EEG) and the evoked response (EP). Whereas the EEG patient state index (PSI) [3], that describes quantitative and topographic EEG changes, and EEG classification to different stages as used in the Narkotrend™ [4] were introduced only recently and thus scientifically less good documented, the majority of information about anaesthesia depth monitoring is presently based on the EEG bispectral index (BIS) and auditory evoked potentials (AEP). It is important to note, that the key issue in CNS monitoring remains the quality, artifact robustness and baseline stability of the primary bioelectrical signal presented to subsequent processing and analysis [5].

*Auditory evoked potentials (AEP)*

Evoked potentials are the non-random components of the electroencephalogram which follow a brief sensory stimulus. Of particular interest in the monitoring of the anaesthetic effect are the early cortical responses to auditory stimuli (mid-latency auditory evoked responses), which have been shown to be extremely consistent in terms of different anaesthetic drugs and

increasing drug concentrations of these drugs, with the exception of Ketamine and Benzodiazepines [6]. Processing of AEP biosignals usually consist of signal acquisition, signal transformation, parameter selection and signal classification. In this context a couple of approaches have been successfully studied to describe an index or parameter based on the auditory evoked response, such as the auditory evoked potential index (AEPex) [7], the autoregressive adaptive modelling (AAI) [8], Forty-hertz midlatency auditory evoked potential activity [9] or wavelet analysis of middle latency auditory evoked responses [10]. One of the problems with using evoked potentials for monitoring is the small size of the bioelectric signal, necessitating a prolonged period of averaging between measurements. This has been partially overcome by introduction of a rapid extracting procedure, that enables extraction of the AEP within 15 sweeps, known as the autoregressive model with exogenous input (ARX, implemented in the AAI). It could be demonstrated that the AEP correlates well with a clinical sedation scale (MOAAS) both with ARX and moving time averaging (MTA), but that the ARX method produced a significantly shorter delay than the MTA [11].

During the last decade, there has been a large number of studies, which tried to validate the AEP in the context of clinical anaesthesia. Although they were evaluated in a variety of clinical situations and with different drugs and drug combinations, their results appear, with only a few exceptions [12], quite consistent. The essence is, that in comparison with other electrophysiological variables, auditory evoked potentials both better indicate the arousability of a patient in response to stimulation and better discriminate the transition from consciousness to unconsciousness and vice versa [13,14], whereas processed measures of the EEG, like the bispectral index (BIS), are better correlated with increasing drug concentrations [15]. This lets us suggest, that both measures are valuable, but reflect different functional parts of the cortico-thalamic neuraxis.

The evolution of quantitative monitors of “hypnosis” tempts one to consider automated control of anaesthetic administration. Closed-loop control of anaesthesia has awaited the development of a sufficiently robust monitor. New designs for automated anaesthetic administration have been successfully evaluated using mid-latency auditory evoked potentials as the input signal [16]. These systems are able to provide an unbiased control method of anaesthesia effect when used in pharmacodynamic studies [17]. Furthermore, results of interaction studies utilizing AEP have revealed more insight into the quantitative contribution of opioids to general anaesthesia and hypnosis [18,19] and have supported some physiological processes. It is now highly evident that the degree of AEP suppression reflects increasing levels of unconsciousness and amnesia produced by hypnotic anaesthetics, whereas other states of unresponsiveness, such as the effect of higher opioid concentrations is less good represented by changes in AEP [20].

*Bispectral Index (BIS)*

The bispectral index monitor has been ongoing developed since 1992 with the premarket approval by the FDA in 1996 (Aspect Medical Systems, Inc., Natick, MA). The bispectral analysis is a further computation of time domain and frequency domain parameters of the spontaneous electroencephalogram. In general, Fourier analysis determines the phase of the various wave components starting at the beginning of the epoch, whereas the bispectral analysis determines the correlation between the phases (harmonics) of the various wave components of which the raw EEG is built. The bispectral analysis considers the relationship between the sinusoids at two frequencies $f1$ and $f2$ and a modulation of these two $f1+ f2$. For this set of three frequency components the bispectrum can be calculated on the basis of the phase information or bicoherence (BIC $f1,f2$) and the sum of the magnitude of the 3 members known as the real triplet product (RTP $f1,f2$). Finally, the bispectral index then is composed of time domain, frequency domain and higher order spectral parameters. In this way the BIS is a computation of the burst suppression ratio (BSR) and QUAZI, two time domain derived parameters, the beta ratio, a frequency domain parameter defining the power in the 30-47 Hz

band relative to the 11-20 Hz band, and lastly the SyncFastSlow parameter determined from the bispectrum as the ratio of bispectrum peaks in the 0.5-47 Hz band relative to the 40-47 Hz frequency band [21]. In general, the Bispectral Index Scale (BIS) reflects the awake state at values exceeding 95, a state of sedation at BIS values of 65-85, an arousal state depression suited for general anaesthesia at BIS values of 40-65 and burst suppression patterns become evident at BIS levels below 40.

The effect of various anaesthetic agents on the bispectral index scale appears to be agent specific. Hypnotic agents like propofol , midazolam or thiopentone have a stong depressant effect on BIS, inhalational anaesthetic agents propagate an intermediate depressant effect, whereas opioids and xenon have little or no influence on the BIS at clinically relevant concentrations. Lastly, nitrous oxide and ketamine appear to have paradoxical effects on the BIS [22]. There are some technical drawbacks in BIS monitoring. Electrocautery will make the BIS disappear or increase, pacemakers and TOE Doppler probes have been described to increase the BIS as well. EMG activity has been claimed to increase the BIS, but later versions like the recent XP version may be less susceptible to this. Furthermore, hypothermia decreases the BIS by 1.12 units per degree Celsius decline in body temperature.

In summary, bispectral index monitoring is useful for the intraoperative tracking of the level of hypnosis and unconsciousness, especially during high hypnotic-low opioid anaesthesia. It allows for an improved titration of hypnotic agent requirement and may lead to a reduced consumption of anaesthetics and improved recovery [23]. No data yet provide sufficient prove that BIS may predict anaesthetic depth or may be used to predict patient responses to noxious stimulation. Similarly, no real evidence exists that bispectral index monitoring reduce the incidence of awareness.

**Conclusion.** Until now, no experimental or commercial device designed to monitor depth of anaesthesia, fulfils all requirements to quantify clinical anaesthesia. However, there have been encouraging advancements in technology that offer robust signals both from the EEG and the evoked response, which have successfully been transformed and implemented in versatile monitors suitable for the OR environment. However, the performance of all of these still lack to be equally reliable in all patients and conditions. Whereas CNS monitoring with EEG derivates or AEP will definitely contribute to an improved patient care by the anaesthetist, its potential to detect and subsequently avoid intraoperative memory formation and recall remains to be demonstrated [24,25,26].

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## Monitoring neuromuscular blockade – actual considerations

**Pühringer FK, Rex C, Renner M, Binder U, Kazmaier F**

Klinik für Anästhesiologie und operative Intensivmedizin, Klinikum am Steinenberg, Reutlingen, Germany

Mechanomyography has been stated as the gold standard in neuromuscular monitoring at the "Intenational Neuromuscular Consensus Conference" in Copenhagen in 1995 (1). Nevertheless, to collect all data online and to create a clinically useful "target controlled infusion" TCI system remained an open target for the future.

The relaxometer received an upgraded software version to the one published in (2), to run on IBM-compatible laptop, and a closed loop algorithm has been included. The closed-loop control system is based on fuzzy logic system consisting of 32 fuzzy rules inference over 3 inputs (error, relaxation rate of change, relaxation stability). Fuzzy rules were evaluated and defuzzified to produce a drug output proportional to patient weight. The stability parameter is calculated from the rate of change of the control error. Each fuzzy input has 7 member functions (POS-LARGE, POS-MED, POS-SMALL, ZERO, NEG-SMALL, NEG-MED and NEG-LARGE, except for the rate of change of control error which has only POS-LARGE, ZERO, and NEG-LARGE). The rate of change of control error has fewest membership functions because it is estimated as a derivative of the control error which is quantised by 1%. Additional logic sets limits on the integral component and produces a lockout time within which the controller output is forced to zero after a dose.

The membership functions of the controller were optimised in simulation for maximum performance over 150 randomly generated PK/PD models. Each simulation consisted of 35000 seconds in which at 5 times the set point is changed to some random value between 50% and 95% NMB. Performance error was defined as the squared control error over all 150 simulations with some extra weighting for under relaxation and steady state offset. The randomly generated PK/models for the optimisation were generated using a singular value decomposition technique starting a base set of 17 PK/PD models. (3,4). During the difficult optimisation, the membership functions the fuzzy logic controller were adjusted for maximum performance. After optimisation has completed the optimal fuzzy logic membership functions were placed into the Relaxometer controller software. The system has already been validated (4), and the device is in clinically routine use in Groningen, Innsbruck and Reutlingen at the current state.

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## Bedside coagulation monitoring

**Hansen R, Koster A, Kuppe H, Mertzlufft F, Hetzer R**

Department of Anaesthesiology, DHZB/Charité Berlin, Germany

**Introduction**. Modern anaesthesiology in cardiovascular surgery needs fast and safe monitoring of anticoagulation during cardiopulmonary bypass. The more differentiated pharmaceutical anticoagulation becomes the more sophisticated our monitoring tools have to be. In this study several adaptations of POC-monitoring from whole blood are demonstrated, comparing TAS-analyzer, HMT and new applications on the ACT II device to standard laboratory tests. Analytical data such as linearity, imprecision and correlation to reference method are sufficient and promising to solve even new challenges like direct thrombin inhibitors or the new pentasaccharide.

**Methods**. Anti Xa activity reagents (Hep-test) and ecarin clotting time were adapted to the ACT II device (Medtronics) and compared to standard chromogenic plasma methods for heparin or hirudin. These methods were evaluated with respect to linearity, imprecision and correlation to reference and used for assessing unfractionated heparin or hirudin respectively in cardiopulmonary bypass assisted cardiac surgery.

**Results**. Anticoagulant activity monitoring by bedside tests like TAS-analyzer, HMT, ACT II-applications proved to be clinically satisfying and superior to the kaolin clotting time. Correlation to standard laboratory tests was >0.8.

**Conclusion**. Clotting assays for specific assessment of anticoagulant activity (heparins, hirudin) are well suited as POC-monitoring tools.

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## Electroacoustic monitoring of breathing sounds

**Gurman GM, Cohen A*, Teiman S**

Ben Gurion University of the Negev, Faculty of Health Sciences, Division of Anesthesiology; *Department of Electrical and Computer Engineering, Beer Sheva, Israel

**Introduction**. The danger of one-lung intubation (OLI) is a well-known incident among anaesthesiologists and critical care professionals, especially for the tracheal tube preference for the right lung. The danger of hypoxia , atelectasis, pneumonia and sometimes tension pneumothorax is evident. Currently there is no proved method for detection of OLI. Clinical auscultation of both lungs proved to be an unreliable method of confirmation of ETT positioning . The daily use of

pulse oximetry (SpO2) was reported as not being able to avoid a case of cardiac arrest because of severe desaturation.

Reports on end tidal CO2 (ET CO2) changes during OLI are rather controversial: ET CO2 level decreased , did not change or even increased .Chest x-ray is a reliable method but its results are worthwhile only for the moment the picture was taken. The same criticism could be applied to fiberoptic bronchoscopy (FB) as a method of confirming ETT positioning. A new method, acoustic reflectometry, was used for identifying oesophageal intubation and till now only one case report presented data on OLI.

In the past years various studies have documented the usefulness of using an acoustic sensor for monitoring separate lung ventilation in dogs by using a spectral analysis of the respiratory sounds.

**Methods and Results**. Our first study was performed on healthy dogs. Endotracheal intubation and then intubation of each main bronchi were performed. The position of the tube was verified by using a fiberoptic bronchscope.

As a sensor we used two contact piezoelectric microphones , each on one side of the thorax. The results obtained after partially correction of this difficulty demonstrated that the on-line monitoring of the respiratory sounds signals could offer a mean 83% accuracy in confirming the ETT distal tip correct position. Strong heart sounds in dog were the explanation for this relatively low percentage.

The second study was performed on patients scheduled for a lung surgical procedure demanding the insertion of a double-lumen tube, which permitted separate lung ventilation during anesthesia. In this case, too, the identification of the placement of the tube was done by using a flexible bronchoscope. The data of this study on 11 patients showed a much closer correlation between the bronchoscope and acoustic sensor findings : 92% for the right lung ventilation; 100% for the left lung; and 92% for both lungs ventilation.

Conclusions The electroacoustic monitoring proposed by us proved to be a reliable method for identification of OLI, since a change in unilateral ventilation of lungs produces immediately a change of pattern of the observed parameter, e.g. breathing sounds.

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## Biosensor function in hostile environment


**Trillò, G**

Department of Emergency, Udine Hospital, Italy


The evolution of emergency care in recent years has moved many resuscitation activities to the pre-hospital arena, involving more and more advanced medical activities, comparable to what can and what is done in the everyday life of an Intensive Care Unit (ICU), an Operation Room (OR) or an Emergency Department (OR).

This procedures comprise often invasive procedures whose target is saving the life of patients that are victim of medical and traumatic insults, whose critical conditions may be corrected, they mortality and morbidity lowered, with the appropriate, early aggressive resuscitative manoeuvres.

The monitoring devices that are used in the pre-hospital arena, being that the streets, the patient's homes, the ambulances and helicopters are, for the most part, not especially engineered for being used in such hostile environments, apart for being able to run on batteries.

It is a special problem, for example, the inability to gain and trust the data produced by the biomedical sensors used to transform the patient vital signs in electrical data, since this sensors are mostly not built to be used in the out-of-hospital settings, but are simply systems taken from the ICU and OR to the real outside world.

This "real world" may be in fact extremely hot or extremely cold, sometimes humidity may become simply clear pure water, and dirt is always everywhere, especially on the patient's skin, as well there may be blood and other unpleasant wastes.

Remember furthermore that the use of any monitoring device on emergency transportation vehicles, we will face a nightmare of problems related to the so called "movement artefacts", up to the point of using a monitor on the real shaky and noisy world of an Helicopter. Who can trust the readings of a pulse-oximeter or of a non-invasive-blood measurement device in such conditions?

In preparing this presentation, the author has done a thorough search of relevant medical literature. Well, there is no literature…And this presentation has no direct solution to the aforementioned problems too. It is simply intended to be provocative, and my aim is to raise some interest from the Companies that produce monitoring device in re-thinking the sensor and monitoring technology that we, emergency physicians, use in our everyday life.

At this very moment, when all my sensors fails on board of my helicopter I'm forced to shift to "good-old" clinical eye to evaluate if a patient is perfused or oxygenated depending on the colour of the skin or the presence of a peripheral pulse, but don't you think this is completely unacceptable in the year 2002?

## Operating room data management in Hokkaido University

**Okamura A, Kemmotsu O**

Department of Anesthesiology and Intensive Care, Hokkaido University, Graduate School of Medicine, Kita-ku, Sapporo, Japan

Information technology (IT) plays an important role in economic, social, and medical areas. Considering clinical anesthetic practice, patient data management, including anesthesia record keeping, is efficiently performed by IT. In the past two decades, anesthesia-related IT focused mainly on producing intra-operative electronic anesthesia record keeping system (EARK) [1)]and pre-operative patient evaluation system[2)]. EARK provides us not only accurate documentation of clinical anesthesia practice, but also an abundant database from which we can retrieve educational, clinical and administrative information[3,4)]. Recently, the anesthesiologists' role in the hospital has become expanded from an intra-operative patient manager to a peri-operative physician. Accordingly, EARK functions are required to include pre-operative and post-operative patient information in order to be a complete peri-operative patient information system. In constructing such a system, each pre-, intra-, post-operative phase should be managed as one system by hooking up workstations of each phase to an information network rather than having stand-alone systems for each of the three phases.

Hospital information systems and the hospital laboratory system have relevant patent information concerning the management of anesthesia. Optimal management of anesthetic patient data is achieved by hooking up an EARK with the existing hospital information systems. Patient driven data flow and facilitation of the anesthesia working process can be achieved by implementing a peri-operative patient data management system at each point-of-care. Based on the above

concepts, we have developed a peri-operative patient data management system called HODMS (Hokkaido University Operating Room Patient Data Management System).

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## HL7 communication standards in healthcare


**Knafel AJ**

HL7 User Group Switzerland, Roche Instrument Center AG, Rotkreuz, Switzerland


Health Level 7 (www.hl7.org) was established in 1987 by a number of health care institutes and vendors in USA as a voluntary organization with the mission to:

- Provide standards for the exchange, management and integration of healthcare data that supports the management, delivery and evaluation of healthcare services.
- Create flexible, cost-effective approaches/standards for interoperability of health information systems.

HL7 is endorsed by the American National Standards Institute (ANSI) as health data messaging standard, and by the German national standardization body (DIN) as a 'norm' in health informatics and applications.

The current standard version (2.4) was approved as an ANSI standard on October 6$^{th}$, 2000.
It defines the following areas of health information exchange.

- Patient Administration, e.g., Admission, Discharge, Transfer, and Demographics.
- Orders for Clinical Services and Observations, Pharmacy, Dietary, and Supplies.
- Observation Reporting Observation Report Messages.
- Financial Management: Patient Accounting and Charges.
- Health Care Application Master Files.
- Medical Records/Information Management, Document Management, Services and Resources.
- Clinical Document Architecture.
- Appointment Scheduling and Resources.
- Patient Care – Primary Care Referral Messages.
- Laboratory Automation – equipment, specimen and laboratory inventory management.
- Application control-level requests, transmission of application management information.
- Personnel Management: professional affiliations, educational details, language detail, practitioner organization unit, practitioner detail, staff identification.

HL7 Inc (International) has grown to become an international standards development organization for health information exchange. It has currently 18 international affiliates: Argentina, Australia, Canada, China, Czech Republic, Finland, Germany, India, Japan, Korea, Lithuania, The Netherlands, New Zealand, Southern Africa, Switzerland, Taiwan, Turkey and the United Kingdom.

Version 2.x is implemented at over 93% of US sites with Health IT systems and in many other countries around the world.

In addition to further improvements of the 2.x versions, the HL7 organization works since few years on a new, object model based version of the standard. The cornerstone of the HL7 Version 3 is the Reference Information Model (RIM) – a large pictorial representation of the clinical data domains. The RIM as well as the strict definition of the vocabulary and of the life cycle of events that messages carry, will ensure semantic level of interoperability. The Version 3 is currently being balloted by the HL7 committees.

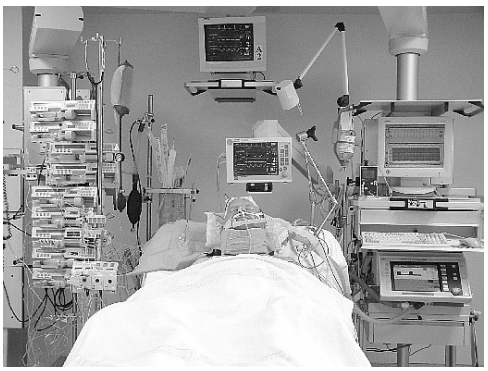
Other groups within HL7 work on Electronic Health Record, clinical context management, security and accountability, syntax for representing and sharing medical knowledge, guidelines interchange, regulated clinical research information management, telemedicine, etc.

## Optimisation of the work-flow on the ICU workplace

**Huber B**

Department of Anaesthesia, University Hospital of Freiburg, Germany

Medical and scientific, just as legal and economical requests are leading to an increasing requirement for more extensive, faster and more detailed documentation in an intensive-care-unit. Last but not least, the introduction of the DRG-System in Germany has increased the necessity in more and better documentation of diagnosis and medical procedures at the bedside.



Since all modern medical devices are equipped with a data interface, it was a given to have the data captured and stored by a computer. One basic question is how to integrate an ICU workplace (consisting of computer, screen, keyboard and mouse) at the bedside which is already overloaded with various medical devices like monitors, ventilators, syringe- and infusion pumps and other medical equipment. The position has to fit most of the users needs and has to be integrated into the normal workflow of an ICU.

Using Centricity QS ® (GE) as Clinical Information System since February 2000, our ICU workplace is paperless. The large amounts of patient data that accumulate daily in a modern ICU had previously been collected on up to ten different pages with hundreds of parameters (per patient and per day) and had to be written by hand into the patient record.

Not only the hospital's patient administrative data are automatically transferred into the computer system. All medical personnel now plan the therapy and interventions and document their care in an electronic record. All updated information is available online (diagnoses, consiliary findings, laboratory data, etc.) at the patient's bedside, including X-ray-pictures.

Instead of producing large patient records the data is now stored electronically. The information is easily

accessible, and when the condition of a patient changes the medical staff can react faster than ever before. To reach a high acceptance from the users, the system has to be easily configurable to fit the needs of physicians, nurses, and other caregivers at the bedside. Using a transponder technology optimises the logon procedure and therefore leads to a higher quality and quantity of data entry.

To optimise the information transfer during the physician rounds or student lessons, we are using a mobile notebook.

**ERGÄNZEN: Blaser J**
**The Zurich CIS-solution: client server architecture**

## Clinical data management systems – defining the process flow requirements

**Marsolek I, Backhaus C, Friesdorf W**

Department for Human Factors Engineering and Ergonomics Technical University of Berlin, Germany

**Introduction**. Growing technological possibilities and administrative requirements have increased the documentation work load within the OR and ICU dramatically. The improvement potential, that can be achieved by introducing an appropriate data management system, is obvious. But the past has also shown, that many systems focus the optimization of very specific work areas only. Sustainable concepts according to the requirements of the entire patient and information flow are rather seldom. Instead an insufficient interaction and missing harmonization between different systems [1] often hinder a systematic process flow support. Furthermore aspects concerning the user acceptance are often not sufficiently integrated while introducing such a new system. As a result the clinical staff starts to complain about the usefulness of the introduced technology. The reason is often not only an inadequate system's usability and functionality but also an inappropriate training and introduction program de-motivating the clinical staff. Instead the goal of an efficient system's introduction has to be a sustainable staff motivation besides a measurable and lasting process flow optimization. In this context the following ergonomic aspects are essential for introducing a new data management system efficiently:

Achieving process transparency: Understanding the entire momentary process flow as a basis for the definition of an optimized version, which has to consider all possibilities of a new data management system as well as all possible work system changes in the near future.

Planning process orientation: Defining the requirements for the new data management system according to the entire optimized process flow and therefore avoiding an insufficient solution, in which only specific work areas are supported.

Forcing staff participation: Integrating the knowledge of the clinical staff during the entire definition of the optimized process flow for increasing the later user acceptance.

**Methods**. A basic method for realizing this strategy is the participatory process flow analysis, which is based on a systematic integration of the involved clinical staff [2] and the following project phases:

- Visualizing the momentary process flow by using a common process language
- Identifying the existing strengths and deficits within the analyzed process flow
- Defining the current and future requirements for the new data management system
- Simulating and discussing possible process flow changes by different alternatives

- Starting a systematic training and introduction program as soon as possible
- Evaluating the optimization and establishing a continuous process flow management

**Conclusions**. The systematic integration of the existing knowledge from all process experts is absolutely necessary for an innovative and sustainable process flow optimization. At the same time only the systematic staff participation can help to increase the user acceptance for necessary changes within the present process flows [2].

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## Effectiveness of simulation-based training of anaesthetists


**Berkenstadt H[1,2], Barsuk D[2], Perel A[1], Ziv A[2]**

Department of Anaesthesiology and Intensive Care[1] and Israeli Center for Medical Simulation[2], Sheba Medical Center, Tel Hashomer, Israel


Simulators are widely used in aviation and military training, and in recent years also in anaesthesiology and intensive care medicine. Benefits of simulation based anaesthesia training includes - training in uncommon critical scenarios without putting patients at risk, safe and structured learning from the results of errors performed during training, and team training of operating room crew. Although the cost of simulation based training is high, there is currently no conclusive evidence that it improves patient outcome. Furthermore, studies in this field are difficult to conduct since adverse effects during anaesthesia are uncommon, performance assessment is not a trivial task, and outcome depends on multiple contributing factors. However, some evidence supporting the value of simulation-based training does exist:

1. Trainees' feedback on the realism of the simulation environment, the relevance of training to clinical practice, their satisfaction from the training, its positive contribution to their professional confidence, and the influence on post training practices are important in the evaluation of simulation scenarios. This important tool is used routinely, and questionnaires are given to trainees at the end of and after few weeks of simulation-based training. These questionnaires demonstrated high satisfaction from training and impact on post training performance by anaesthesiology residents, other physicians, nurses and paramedics trained in various anaesthesia, emergency medicine and intensive care scenarios.

2. Simulation training was used to study the errors performed by anaesthetists during critical events. Lately, simulation was used also to evaluate gaps in knowledge, interpretation of data, synthesis of information, and development of treatment in anaesthetists with lapsed medical skills. Such insights cannot be gained by oral or written assessment tools, and is important for the understanding of mechanisms leading to errors in anaesthesia and for further development of tailored education and more focused training. We have studied, for example, the common errors performed by ATLS graduates during airway and breathing management while treating trauma casualties, and changed the training curriculum accordingly.

3. Over the years, simulation scenarios and evaluation tools have been developed and validated. Using these tools, the difference in performance according to seniority in anaesthesia, and improvement in performance after repeated simulation training have been demonstrated.

4. Simulators have been also shown to enhance cognitive teaching. The use of computerised screen-based simulator, for example, was shown to improve the retention of ACLS guidelines beyond the use of a textbook review. In our institution, advanced simulation improved the knowledge and understanding of the pulmonary artery catheter and mechanical ventilation among intensive care nurses. We are also using simulation for the training of anaesthetists to treat non-conventional warfare casualties.

In summary, literature supports the feasibility of using simulation techniques in various fields of anaesthesia and intensive care. The lack of conclusive evidence to the effect on outcome is still missing but "No industry in which human lives depend on the skilled performance of responsible operators has waited for unequivocal proof of the benefits of simulation before embracing it" (1). However, the limitations of simulation-based training should be recognised and their use must always be carefully designed and viewed as an important supplement to traditional training methods and as a complementary and safe tool in medical education.

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## Shift planning for residents in anesthesia – the Zurich experience

**Baumann, P**

Institute of Anaesthesiology, University Hospital Zurich, Switzerland

**Introduction**. There is an increasing interest and concern about the working conditions for residents in hospitals throughout the western world. A lot of sometimes passionate and emotional debate has been invested and the subject has become a considerable political issue since there is quite an amount of money involved: For example the reduction of the weekly working hours from 80 to 70 h for each resident at any given hospital causes an approximate increase of costs of residents' salaries of 15%! The debate is about a doctor's role in the society and how much time a doctor should have left for social and family life but it also is about patient's safety and comfort: What for instance is the potential risk of a chronically fatigued doctor working overnight without rest every 3$^{rd}$ night?

This discussion has developed a bit further in Europe than in the US where it so far remained to be the playground of a couple of strayed members of the medical society. The only US state so far that has limited work hours for residents is New York where there is a maximum of 80 h/week and a maximum of 24 h for rota duration. The fact that almost every hospital that is controlled on a random basis for their adherence to the rules cited is fined for their violation speaks for itself. In Europe, reluctantly also in the UK under the influence of EU regulations, the situation is getting regulated increasingly: actually there's a maximum of 56 h/week, this number will be reduced to 48 h/week by the year of 2003. In Germany for instance in many hospitals there is an official work hour limit of 38 h/week, just like for any other profession, too.

*Development in Zurich*: In the recent years there has been considerable and increasing pressure on the hospitals to regulate and reduce work hours for residents. The major part of the doctors employed by public hospitals nowadays is organized in a national association (VSAO) with regional subdivisions very much like a labor union. In some cantons there have already been installed some regulations by the government after some initiatives of this association. In the canton of Zurich, the most populated canton in the country, the situation has got out of hand for a moment in 1999 when discussions with the government got stuck. The doctors went on an administrative strike by refusing to do any paperwork needed by the hospital's administration to write their bills to be refunded. The resulting political pressure on the government led to a contract aimed at the reduction of working time to a maximum of 54h/week by the year 2000 which in

addition has to be reduced by 1h/week every year until a level of 50 h/week will be reached by the year of 2004.

Within our institution this evolution created some pressure to reform the whole system of academic staff planning. Up to that time there was an average working hour level of just about 60 h/week and sometimes people had to be working continuously for 24 hours. In 1999 a group of doctors has formed up who felt concerned about worsening mood and motivation among the majority of the staff, which in part was ascribed to the duty rosters and their designs: High levels of workload in terms of working hours, with regard to rosters a grinding lack of reliability and frequent changes in the ultimate minute. The publication of the new rosters frequently did not take place until the eve of the new month. In the following there will be a short description of the project to reorganize staff planning at our institution.

**Methods**. Definition of the goals to be achieved by the reformation:

- Reduction of the weekly work hours
- Elimination of shifts of 24h and more
- At least 2 full days off in every 7 days
- Equilibrated distribution of duty periods
- Improved transparency
- Improved reliability
- Improved motivation and identification with the institution

What were the requirements for this future system?

- PC-based solution in a networked environment to guarantee accessibility
    - From any place hospital-wide
    - At any time
    - For anybody entitled
- The newly composed roster plans in comparison to the old ones should be looking alike as much as possible to enhance their acceptance in the audience

Many other elements could have been thought of to add: possibilities for users to enter data and requests (e.g. positive or negative wishes for duties, holiday reservation etc.), looks, interchangeable data format and so on. Finally, the most important and convincing argument was the fact that we were lacking of sufficient funds. So we had to limit to the means already at hand: a network of personal computers accessible in every remote corner of the dispersed geography of our institute.

In a similar way the question was answered whether

1. To have programmed an entirely new application
2. An adaptive programming within an existing relational database (such as MS Access or FileMaker or similar)
3. A simple solution that can be managed by the staff themselves who are no computer specialists. For example a spreadsheet application like MS Excel, which is furnished with lots of data handling features, comparable to the possibilities offered by relational databases.

Apart from the fact that it’s all just a question of money we also had some other criteria that directed us the same way:

- Practicability: who of our team is able to do what? Are there tasks that must be given to an external firm? Or is the domestic informatics department able to meet the needs?
- Resources: Computers, staff, time (what is the deadline? when do we want to start?)

Very clearly there was none but one possible solution to choose: the slim-line, home made, self-administered, cost-neutral way: The use of a PC with spreadsheet software (MS Excel® 2000)

Realization phase - The Tables to choose and Their Look

*Overview*
x-axis: all the residents employed at the institute together with information about their former education and professional experience

y-axis: time-scale – single days

found in the table: the function of the given person above on a given day of the year

This is the central and most important table with all the automated statistics integrated that allow both more control and more transparency

*Emergency duties* (around the clock; 7/7 days)

x-axis: different shifts and functions provided; y-axis: time-scale by single days

found in the table: name of the person who is in charge of a given function (listed above) at a certain time

This table is almost entirely automatically generated out of the 'Overview' sheet by an interposed index table, which translates the structure of a separately developed scheme, which says how to employ the people on emergency rotation. It is organized in a self-repeating manner on a weekly basis. The scheme remains the same and the staff that changes every week is inserted automatically into the corresponding positions.

*OR staff* (day shifts only; Monday through Friday)

x-axis: name of the member of the staff; y-axis: time-scale by single days

found in the table: OR-section where a given person (listed above) is working at a given day

The structure of these 3 rosters does not really cover all the needs or questions that should be answered by this source of information. Since in order to keep acceptance up it has been clear strategy to stick as close as possible to the design and concept of the previously used plans we preferred to postpone the changing of designs to a later moment.

**Results** and experience up to date

1. Although not statistically analysed we realised a prominent reduction of the average working hours per week and resident that is characterised by a sudden onset right at the time of the introduction of the new planning regimen in May 2000.

2. According to the results of a simple questionnaire that was distributed about 6 months after the start the following can be stated (return rate approx. 40%):

- Generally the new system offers more advantages than disadvantages
- The return to the previous system was not desired but by one person
- The vast majority of residents felt some improvement in the subjective quality of life

- The concept of shortened periods of night shifts (2 sets, one of 3 and one of 4 nights instead of one entire week) is dividing the opinions in two almost equally strong opinion groups
- A huge majority had the impression to be working substantially less hours than before
- The duration of a shift (night or day) is accepted as reasonable
- The readability of the rosters is generally judged okay or good
- People feel that there are still time resources that could be profited of much more
- Planning ahead for holidays or other absences has become even more troublesome

3. The new system has proved quite trouble sensitive when the total amount of residents employed falls below the minimum it takes to fill all the positions provided by the plan. In this situation the effort it takes to provide a balanced roster is not only doubling but also multiplying.

Discussion. In Europe there is a growing political interest to be found in working conditions of doctors, especially in their sometimes incredibly high amounts of work hours. An increasing political pressure has emerged out of this interest to reduce doctors' working hours dramatically. Advantages and disadvantages of reducing weekly work hours are increasingly debated.

To be able to modify the existing system it is necessary to develop suitable planning tools, which permit more efficient deployment of the personnel at disposal than in the past; tools, which guarantee the adherence to the politically defined guidelines; tools, which improve transparency and therefore create more justice.

In Zurich we tried to accomplish an improved roster planning by the consequential use of spreadsheet software on the basis of a desktop computer. According to votes in the literature there is a number of advantages in the use of a spreadsheet application instead of entirely newly programmed applications. Among these advantages of spreadsheet tables appear independence from external (software) companies, much less money involved, better calculability of the expenses to be expected for the development of the tool. In addition these software tools offer the opportunity to simulate quite complex interrelations by simply changing some parameters serving as the basis of the models.

Apart from these arguments we suffered from the lack of money and from the lack of advanced programming knowledge, two arguments that anyway would have brought us to the conclusion to go the spreadsheet way. Using this method we managed at least to achieve the aim of meeting the criteria dictated by the political authority: 54 hours/week, at least 2 days off/week, no more 24 hour-shifts, at least 4 weekends off in every 3-month-period. Beyond this it can be said that the people - according to a little questionnaire distributed half a year later and albeit probably statistically not significant - generally speaking felt a little more quality of life, thought they worked a little less and felt a little more comfortable with our new way of roster planning.

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## Computer assisted operation theater management

**Schulte Steinberg H, Karrenbauer U**

Clinic of Anesthesiology and Surgical Intensive Care Medicine, Klinikum Augsburg, Augsburg, Germany

The Klinikum Augsburg is a hospital of the highest level of care with 1600 beds, treating 56000 inpatients and 78000 outpatients each year. Twelwe surgical disciplines perform 30000 procedures within the 40 various operating theaters. Since most of the organization as to where and when these procedures are performed is managed by anesthesia, a computerized system was installed to assist in coordinating this wealth of information.

All of the operating theaters, anesthesia induction suites, ward offices, as well as several other strategic positions were equipped with computers linked by a network to a central server. This server runs the OR-program OpDIS® developed by the German medical software company C.a.r.u.s. (Bornbach 9, Norderstedt, Germany). The peripheral computers run OpDIS® as clients of a central server. The program allows for storage of all the necessary patient and procedure relevant documentation at the site where the procedure is performed. This guarantees to keep any loss of information to a minimum. Completed documentation protocols are transferred online to the finance department of the hospital, ensuring that billing to the health insurance of the patient is correct, complete and in time.

All prospective procedures are planned into the system in advance by the individual surgical unit. The relevant information on diagnosis, procedure, positioning of the patient, need for special equipment, etc. is incorporated at this time. The anaesthesia relevant information is then added and the procedures are arranged to form the next days operation theatre schedule. When the operation is performed all information pertaining to time is added to the patients computer documentation at the moment of its occurrence. This allows the computer system to generate a picture of what is happening where at any given time. The online information is of great help in the daily coordination of all operations. Everyone who is involved in the operative procedure of a certain patient knows exactly what is needed where and at approximately which time. Urgent or emergency procedures can easily be integrated into the existent workflow. The installation of this system has greatly simplified the control of the daily surgical workload, as well as the quality of the necessary documentation has increased.

## Impact of diagnoses related groups (DRG) based reimbursement on anaesthesia

**Pollwein B**

Klinik für Anaesthesiologie, University of Munich; Germany

Diagnosis related groups refers to a patient classification system that provides a way of describing the types of patients a hospital treats (its case mix). DRGs were originally developed by a group of

researchers at Yale University in the late 1960s as a tool which generates case groups, based on statistical-economical methods, to help clinicians and hospitals monitor quality of care and effective utilization of resources. Inherently, DRGs have nothing to do with reimbursement. But by historical accident, DRGs were chosen 1983 by Medicare in the United States to pay hospitals. Since DRGs hit the scene as part of a reimbursement scheme, DRGs became linked with reimbursement in many people's minds. Briefly, the DRGs work by taking the ICD-Diagnosis codes and grouping these into a more manageable number of meaningful patient categories (500 to 600). Patients within each category are similar clinically and in terms of resource use and costs.

General impact of DRG based reimbursement

Using diagnosis-related groups, hospitals were paid a certain amount of money to take care of a patient determined by the diagnosis they have. This method encourages shorter hospital stays, getting the patient home as soon as possible, while providing the care needed. Although this approach helps to control costs, the potential problems with this reimbursement system include:

1) Shorter stays than truly needed (which can cause readmissions).
2) Tests or procedures that are needed may not be performed.
3) An increased need for care after discharge.
4) An increase in outpatient visits due to substituting inpatient admission with outpatients visits.
5) Quality of treatment decreases.

Special impact on Anaesthesia:

1) Time pressure during pre-anaesthetic evaluation and preparation.
2) Special tests that are needed for risk evaluation may not be performed.
3) Postanaesthetic complications may increase.
4) Potential more risky ambulant anaesthesia.
5) Quality of anaesthesia delivery may decrease.

To avoid these unwanted effects it is necessary to take reasonable precautions:

1) Ambulant preanaesthetic evaluation and preparation including cooperation with general practitioner if possible.
2) Implement guidelines for preanaesthetic evaluation.
3) Adapt and enforce patients information to recognize possible complications.
4) Adapt anaesthesia techniques and postanaesthetic care.
5) Establish adequate documentation and quality management.

## Architecture of the operation theatre

**Held J**

Institute of Hygiene and Applied Physiology, Swiss Federal Institute of Technology, Zurich, Switzerland

**Introduction.** Known as the hospital’s most expensive and for sure as a high-tech area where complex work procedures must be performed with high efficiency and safety, the operation theatre is of particular interest in the architect’s planning process. The presented work will show methods

to support this planning process. Those methods have been applied in planning projects of new operation room (OR) facilities.

**Methods**

a) A variable layout model (VALAMO) was used for knowledge expression in user-interviews of 4 operation room facilities (University Hospitals in Zurich (USZ), Berne, Rochester/Minnesota/USA and Leuven/Belgium). The VALAMO is a set of scaled magnetic objects which stand for the actors (patients, OR-team members) and a metallic white board which represents the architecture of the OR facility.

b) A work posture and equipment analysis was used to determine workspace for a mobile emergency concept.

c) A computer supported analysis (FIT-System) is used to visualise OR facility work flows. The analysis covers 27 anaesthesia preparation work flows in the USZ.

d) A computer data base is designed to make the users' knowledge and work system's characteristic transferable.

**Results**

a) VALAMO interviewing provided an insight into the facilities work flows correlated to the advantages and disadvantages of the architecture. In two cases preparation rooms are no longer in use due to personal cost restrictions. Large OR facilities take profit in work efficiency by principles of feed forward and feed back in the architecture of clusters.

b) Work posture analysis led to a new definition of work space related to tasks of anaesthesia and emergency treatment. It showed that more work space is needed than some planers may extrapolate from normative publications.

c) FIT-System work flow inspection showed that the preparation and induction of the patient is a high diversification of parallel tasks in team work.

d) Computer data base design led to an internet system (named MEDINO, management of ergonomics and design in OR-Facilities) to manage up to now 597 user statements structured by four hospitals and 19 aspects of system's design.

**Conclusions.** Despite of a respectable number of design and redesign projects of OR facilities work systems, knowledge is still missing in the planning processes. Experts of ergonomics can analyse and express such knowledge. But this is most useful in the beginning of design processes and therefore requires the planner's awareness. As such work system knowledge must include users' knowledge, system layout knowledge and work flow transparency, computer data base system can help to collect it, but cannot make the co-operation of users, planers and experts in ergonomics/work science unnecessary.

## Cooperation between anaesthetist and surgeon: the safety aspect

**Scheidegger D**

Department of Anaesthesia, University Hospital, Basel, Switzerland

The major cause in accidents and incidents in aviation is the absence of consistent and adequate team behaviour in critical phases. It is not the lack of skills, but rather the failure of behaviour relevant to team performance that contributes significantly to a mishap.

In the past 10 years, industry has invested heavily into developing technology and technical training to reduce the overall risk. A lot of new monitoring systems and other technical equipment have been introduced into the OR, without any impact on the number of critical incidents. Due to

the more complex working situation, the introduction of these technical systems may even be responsible for new additional critical incidents. The medical training today in the OR is primarily a accumulation of personal skills. The area of systematically developing critical behaviour standards and training tools to implement such standards has been totally neglected in the operating room environment.

In aviation - another high risk environment - such behavioural training was developed, implemented and enforced by law.

Most behaviour is learned, being shaped by e.g. national, professional and company/hospital culture, education and also internal value system. This in turn has to do with the concept of self and others and with the motivational structure of the individual. Although these interactions are complicated, the effects of these links are evident in our life in the OR. Thus a skilled professionalism is not only required in the area of technical, e.g. surgical or anaesthesiological skills, but also in the area of these “non-technical skills”.

In aviation it was seen as an important step in improving flight safety to systematically develop methods for identifying important attitudinal links, improving relevant non-technical team skills, and generally learning about this area. Unfortunately we lack such a training in the OR. In a plane only two professions are handling the customer, pilots and flight attendants, whereas in the OR we have at least five different professions, that deal with the same patient, therefore we also have five different professional cultures, that try to work hand in hand in the same work process. In the OR we have co-workers from many different countries, which means not only different professional, but also national cultures.

It is therefore difficult to understand, why aviation was forced by law to implement such training courses, whereas in an operating room, where the risk for interpersonal conflicts is much higher, no such training even existed!

Crew Resource Management (CRM), the training course used in aviation, is seen as the method that ensures the optimal use of all available resources, including human resources in a team. Within such a team, categories of relevant team process include cooperation, leadership and managerial skills, situational awareness and decision making. The behavioural standard e.g. for decision making includes points like “Option Generation”, “States alternative course of action” or “Asks fellow crew members for options”.

Before full compliance with all these relevant behaviours can be expected, awareness for such a process must be initiated, knowledge of the relevant facts must be transferred and individuals must be trained in the non-technical skills. Standards for such training, for trainers and evaluation methods have to be developed. We know from the results of our critical incident reporting system, that over 60% of all our incidents are due to failed teamwork within the professionals working in the OR. A 3-year experience with such a training course for OR personnel and its impact on risk management will be presented. Training sessions in a full scale OR simulator are also essential for the cooperation between Surgeons and Anaesthesiologists.

## Integrative concepts for the operation room

**Friesdorf W, Marsolek I, Göbel M**

Department for Human Factors Engineering and Ergonomics Technical University of Berlin, Germany

**Introduction**. The operation room (OR) work system is determined by the design of space, work places, devices and material, the clinical staff, the organisation and the patients (i.e. the cases which have to be treated). Cost pressure forces a rationalisation of this work system.

**Problem**. A core element of rationalisation is planning and standardising work, which is difficult and limited for the work system OR due to its variability. The work system OR is highly complex. Rationalisation is dealing with this complexity by using simplified models for a system. But simplified models focus only on selected aspects. If significant interdependencies are hereby neglected a system break down might be pre-programmed.

**Goal**. Our goal is the development of an integrative concept, which enables a sustainable rationalisation of the clinical work system based on a balance between simplicity and complexity. There is a variety of definitions for complexity and its measurement. Considering our goal we have to focus on the complexity, that is linked to the uncertainty of the problem solving (decision making) [1]. The degree of complexity depends on the unknowns, which would be necessary to solve a problem unequivocally.

**Approach**. "Ergonomics (or human factors) is the scientific discipline concerned with the understanding of interactions among humans and other elements of a system [...] in order to optimise human well-being and overall system performance" [2]. This ergonomic systems approach offers several strategies to reduce complexity: The hierarchic system structure defines layers with different granularity. Strategic zooming through the layers gives an overview as well as a detailed insight into subsystems. The definitions of quality (task fulfilment vs. task setting) and efficiency (quality vs. resources) are valid for all system layers. They can be related to one individual, to a clinical team or the entire OR.

A different point of view leads to four model classes:

1) Task models (what are we doing?)

2) Structural models (organisation, architecture, etc.)

3) Dependency models (e.g. the quality of results is influenced by the staff motivation)

4) Process models (how do we do things?)

For their integration a meta-model is necessary consisting of a patient oriented process model as a core. Hereby three process classes require different optimisation strategies:

Tertiary processes (e.g. an indirect patient treatment support like sterilisation or cleaning) belong to tasks, which can be outsourced. The rationalisation of the underlying processes then becomes part of an external company, which is the easiest way of simplification. Secondary processes (e.g. a direct patient treatment support like the Lab or the OR management) include typical logistic problems (e.g. use of limited resources). A process analysis and standardisation has to be the way for simplification here. Primary processes (concerning the direct patient treatment) have the highest complexity. While standardisation reduces complexity, a simplification might be dangerous. Instead a systematic development of individual and team competence is needed for coping with complexity in the long-range.

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## The hazardous operating room: worker's health (SiGOS)[1]

[1] SiGOS - Safety and workers' health in the operating room ("Sicherheit und Gesundheit im Operationssaal"); Research project funded by the Berlin Accident Insurance Association ("Unfallkasse")

**Göbel M, Zschernack S, Friesdorf W**

Department for Human Factors Engineering and Ergonomics Technical University of Berlin, Germany)

**Introduction.** Workers in the operating room are exposed to hazardous conditions and situations. According to statistics, the frequency of accidents in the operating room is about ten times higher than in chemical industry (although cost per accident is much less). But, only few and specific attempts were made to reduce personnel risks in the OR. This is due to the complex and variable task structure, in conjunction with an attention conflict between patients' safety and workers' safety.

**Risk Analysis.** Analysing the data of work related accidents shows that (1998/99 in Berlin, Germany) 57% of all work accidents in OR were caused by cutting and sticking with sharp instruments; 11% of all accidents originated from clamping and squeezing; 10% were hit and crash accidents. But, the data of work related accidents only shows the consequences of hazards in the OR, and it does not show all the consequences. Beside the fact, that exiguous accidents (which occur frequently!) were not reported in most cases, lesions caused by long term and frequent execution of stressing tasks (e.g. lesion of lumbar spine) at best randomly correlates to accidents. Accessing health impairments by analysis of sick-lists lacks of complementary information, and, furthermore, sickness relates only partially to professional stresses. To sum up, there is only few objective data available on hazards in the OR. On the subjective side, the awareness of hazards is strongly affected by adaptation to regularly present risks. However, subjective hazard rating may deliver important information for prevention approach.

**Risk Prevention Approach.** Due to the very flexible work processes in the OR, strict rules for behaviour and organisation – as it is practised in other domains - would conflict with patient treatment demands, and, thus, cannot be implemented according to a simple pattern. Workers in the OR rather have to act responsible concerning personal hazards. This individually requires risk awareness, knowledge to avoid hazards, and skills for communication and cooperation with respect to hazards. Additionally, organisation and infrastructure should provide – or at least allow – working conditions with few hazards. That's theory. In clinical reality, many people talk about safe working conditions, but none of the actors thinks about during work. Furthermore, we even do not know how to act (except for technical security aspects).

**Information technology and clinical hazards.** Could information technology support secure work in the operating room? Fundamentally no. But, looking at the risks in detail, most hazards origin from inadequate arrangements. Some examples: (a) Slipping on wet floors occurs when a room is used too early after wiping. (b) Hitting is provoked if equipment is sized and arranged inadequately according to the space in the operation room. (c) Human error drastically increases if time stress or work strain exceeds individual limits. Although we all know about that, neither those facts are focussed during work (because attention is concentrated to the patient) nor we do have an total view on all processes and individuals interacting with each other. At this point, electronic process management – if applied extensively - would be a key tool to support actors for secure arrangements. The "only" thing we would need is to compute process data according to personal and infrastructure resources. Workers would be kept aware about total personnel and technical resource states, and, thus, they could be warned in case of potentially hazard constellations. But, before, OR management would try to avoid any critical resource exploitation. To make this true, not only extensive process planning data management would be required, but, in particular, an additional hazard report management system must ensure feedback to establish a control loop. Assuming that secure and human working conditions would significantly improve work motivation and human performance, this would have the uncommon result, that electronic data management and process organisation would actively support human factors concerns.

## From open to closed loop controlled ventilation

**Brunner JX**

Hamilton Medical AG, Via Nova, Rhäzüns, Switzerland

**Introduction**. Patients who have difficulty to breathe may be put on machines (ventilators) that fully or partly breathe for them. In doing so, mechanical ventilators fully replace or partially support the respiratory function of patients in three distinctly different yet sometimes overlapping areas [1]: (A) Ventilation: i.e., elimination of CO2, achievement of a desired arterial pH level, (B) Pump support: support of the respiratory muscles, short- or long-term, (C) Oxygenation of arterial blood. All modes of ventilation offer controls to achieve A,B, and/or C. The pertinent parameters like tidal volume, rate, inspiratory time, etc. are set manually, based on data that is mentally processed by the clinician. Such a process can be termed "open loop control" since it always involves a human being in the control loop. However, part of this open-loop process may be accessible to automation [2].

**Methods**. Adaptive Support Ventilation ASV was conceived to cover areas A and B listed above. As such, ASV controls tidal volume as well as rate and inspiratory/expiratory timing, inspiratory pressure levels, covers paralysed patients as well as spontaneously breathing subjects, allows the clinician to select a risk-level, chooses the breath pattern automatically based on the mechanical properties of the lungs, and implements lung protective rules [3]. Thus ASV constitutes the first clinically usable closed-loop control algorithm to base its decision on actual patient data and not only on clinician input.

**Results**. ASV was investigated in postoperative cardiac surgery patients to assess the number of operator interventions compared to conventional ventilation [4]. The results suggest that with ASV, the need to readjust ventilator parameters is markedly decreased. When used on passive patients with different respiratory system mechanics (normal lungs, restrictive disease, or obstructive disease), ASV automatically chose a ventilatory pattern that was suitable for the particular disease [5]. In a group of cardiac surgery postoperative patients [6] the duration of mechanical ventilation was shorter with ASV as compared to conventional ventilation (3.2 vs 4 hours, median values).

**Conclusions**. Present studies confirm that the key features of ASV are ease of operation for the user and adaptation to the different and variable characteristics and needs for the patient. However, neither ASV nor any other closed-loop control mode of ventilation has been shown to improve outcome.

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## Automatic control of ventilation in anaesthesia. Development and application of a new model-based closed-loop control of mechanical ventilation

**Zbinden A, Martinoni E, Stadler K, Böhlen T, Leibundgut D, Schumacher P, Pfister C**

Department of Anaesthesiology, Section of Research, University Hospital of Bern, Switzerland

**Introduction**. During anaesthesia, in most patients the gas exchange between lungs and capillaries is impaired . The minute volume (MV= f * VT, where f is the respiratory frequency and VT is the tidal volume) has to be adjusted to maintain the end-tidal CO2 (FE'CO2) within acceptable clinical limits. The anaesthetist has therefore multiple possibilities to increase or decrease the minute volume. A patient with severe chronic obstructive pulmonary disease is ventilated differently from a healthy patient, depending on his pulmonary mechanics and the ventilation/perfusion mismatch, thus ventilation settings may be changed intra-operatively. The control of arterial CO2 partial pressure (PaCO2) is important, for example during intracranial surgery, where hypocapnia is required to diminish cerebral perfusion and intracranial pressure. Therefore, maintenance of adequate ventilation is an important task, that has to be controlled and guaranteed.

The development of closed-loop control systems that would have an impact on clinical care is a major challenge. Thanks to the improvement of new technologies and fast computers, the study of automatic systems in anaesthesiology has regained interest . The first example of closed-loop anaesthesia was described by Bickford in 1950 . In the recent decades, different techniques of automatic feed-back control have been developed and increasingly applied to anaesthesia intensive care with the aim of improving the control of anaesthesia and relieving anaesthetists from routine manipulations.

Several attempts have been undertaken to automate mechanical ventilation. Laubscher and colleagues described a PI based controller, where special selection algorithms are used to maintain a target alveolar ventilation by selecting f and VT to minimise work of breathing. This allows to automatically adjust ventilation according to the health state of the patient. However, continuous measurements and analysis of expired CO2, airway pressure and airway flow are required. In 1996, Schäublin and colleagues , described the performance of a fuzzy controller of FE'CO2 for the ventilation of patients by comparing it with manual ventilation control. It was concluded that fuzzy logic feedback was a reliable and safe mode of control. Fuzzy logic systems are able to control a process without the determination of an explicit mathematical model of the input-output relationship.

In this study a new model-based controller for mechanical ventilation is presented. A mathematical behavioural model is used in a simplified form, sufficiently descriptive for control purposes. The performance of the controller is compared to that of Schäublin and colleagues, the evaluation of which had been performed in a similar way. A standardised set of parameters is used to compare controller performance.

**Methods**. After obtaining the State of Berne ethics committee's approval and the patients' written informed consent, seven (out of 13 planned) patients, five women and two men, ASA class I-II, mean age 34.4 (SD 12.5), mean BMI 24.7 (SD 3.3), scheduled for elective general anaesthesia were included in the study. Patients suffering from COPD or whose lungs were not ventilated mechanically and patients undergoing emergency, pulmonary or intracranial surgery and operations lasting less than two hours were excluded.

The patients were pre-medicated with midazolam 7.5 mg p.o. one to two hours before the induction of anaesthesia and omeprazol 40 mg p.o. the evening before the operation. After pre-oxygenation during three minutes, anaesthesia was induced with a propofol bolus of 2 mg kg-1and a fentanyl bolus of 0.3 mg kg-1, given in 30 seconds, followed by a continuous infusion of propofol and remifentanil according to clinical needs.

EMG was measured using a Datex AS/3 – Engstrom NeuroMuscular Transmission Moduleä (Instrumentarium Corp., Helsinki, Finnland) and used as input signal to the closed-loop feedback controller for mivacurium. The desired level of NM block (set point) was set to 90% (T1 = 10% from control). A mivacurium bolus of 0.3 mg kg1 was administered to the patients via an Asena-GHä pump and the trachea was intubated. The closed loop controlled mivacurium infusion and the model-based automatic control for mechanical ventilation were started and anaesthesia was maintained according to clinical needs. Patients, whose mean arterial pressure fell below 60mmHg were haemodynamically supported with fluid infusions and catecholamines. Standard measures during the study included: continuous systolic, diastolic and mean arterial pressure (SAP, DAP, MAP), continuous electrocardiogram (ECG), heart rate (HR), capnography, f, VT, MV, peripheral oxygen saturation (SpO2), peak and plateau airway pressure (PPeak, PPlat), inspiratory oxygen concentration (FiO2).

FECO2 at the mouthpiece was measured with a side-stream infra-red spectrometry analyser (Dräger, Lübeck Germany), calibrated according to the manufacturer instructions and used as input-signal for the ventilation automatic controller. Normoventilation was defined at FE'CO2 = 35 mmHg, hyperventilation at FE'CO2 = 28mmHg and hypoventilation at FE'CO2 = 42 mmHg. All patients were initially normoventilated. After reaching target FE'CO2 and having a measurement period of at least 15 min., the set point was changed: By drawing lots patients were randomly assigned to either group A, who were initially hyperventilated or group B, who were initially hypoventilated. After reaching the new set point, and having a stable measure during at least 15 min the ventilation pattern was again reversed for the two groups. Set-point changes were carried out until the end of the operation. Arterial blood gas analysis (ABGA) was performed at the end of each measurement period in order to establish a reference for the arterial CO2 concentration (CACO2). Data were digitised every five seconds and stored on hard disk.

Mathematical Model, Controller Design

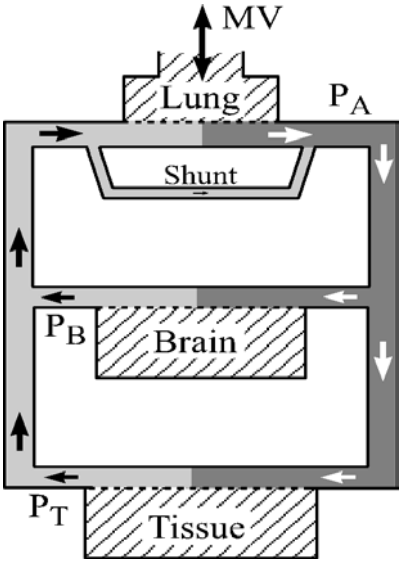


Fig. 1. Compartmental model for control purposes

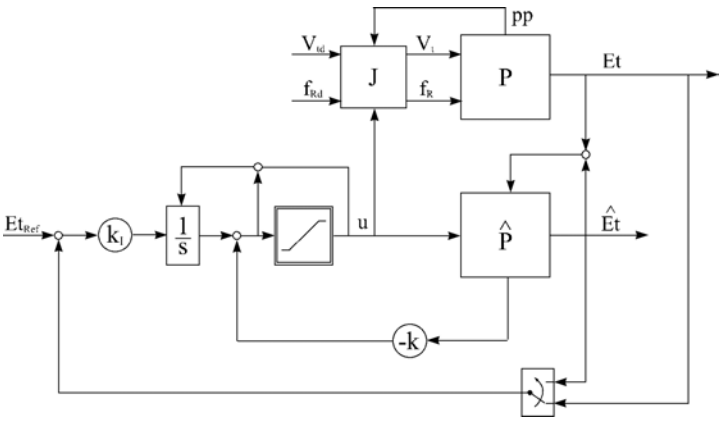


Fig. 2. Structure of the controller with patient (P), observer ( $\hat{P}$ ), state feedback control vector (k), additional integral part (kI), peak expiratory pressure (pp), measured (Et), observed (Êt) and reference (EtRef) end-tidal CO2 concentration, algorithm block (J) with additional inputs from the anaesthetist (fRd) and (Vtd).

The model derived from Chiari11 is shown in Fig. 1, which describes the O2/CO2 exchange in a lung, a brain and a tissue compartment, assuming cardiac output constant, immediate mixing within compartments and in the arterial and mixed venous compartments.

The algorithm is designed to translate the desired MV into appropriate f and VT, which maintains the reference (Etref) while keeping in range the desired settings for f and VT. Additionally, an upper constraint on PPeak is considered. When the constraint is reached, f is automatically increased, thus VT decreases, and PPeak is reduced. A weight parameter shifts the manoeuvres preferably to f or to VT.

The model-based controller approach has an observer system incorporated. In case the measured FE'CO2 is transiently invalid due to sensor artefact, the controller uses the observed FE'CO2 as input signal, therefore increasing the safety for the patient.

The controller was implemented on a real-time control platform, operating with a modified Cicero anaesthesia workplace (Dräger).

**Preliminary Results**. One patient was excluded from the analysis, because, when put on a lateral position for a total hip prosthesis intervention, he developed important lung secretions which necessitated repeated suctioning.

Of the model-based controller group, three patients were in the group A (first hyperventilation) and four in the group B (first hypoventilation). In one patient it was necessary, due to surgical needs, to set the FE'CO2 to 35 mmHg after an hypoventilation phase. The ventilation patterns were then restarted with a hyperventilation phase. Seven mmHg corresponds to the change of one vol % (from 4.5% to 5.5% and viceversa) of Schäublin's study. Schäublin's group comprised 15 patients.

To compare the two groups, a Students' t test was performed. Probability values $p < 0.05$ were considered statistically significant. Data are presented as mean (standard deviation).

Dynamic Performance

The following steps can be compared with Schäublin's study

- Six downward steps from normoventilation to hyperventilation (35 mmHg to 28 mmHg) or from hypoventilation to normoventilation (42 mmHg to 35 mmHg)
- Six upward steps from normoventilation to hypoventilation (from 35 mmHg to 42 mmHg) or from hyperventilation to normoventilation (from 28 mmHg to 35 mmHg)

For these steps, we considered the rise time (time required to move from 10% to 90 % of steady state of the desired change6,10) and the overshoot (the maximum value achieved, expressed as absolute value above the steady state value after a step change of set point6,10, ). Table 1 shows a significantly shorter rise time in the model based controller.

| | + 7 mmHg step change | | | - 7 mmHg step change | | |
|---|---|---|---|---|---|---|
| | Model based | Fuzzy | p | Model based | Fuzzy | p |
| Rise time (sec) | 138.0 (15.1) | 313.0 (90.0) | **<0.001** | 168.7 (22.8) | 355.0 (127.0) | **0.002** |
| Maximum overshoot (mmHg) | 1.0 (0.0) | 1.8 (1.5) | 0.207 | -1.0 (0.0) | 1.1 (1.1) | 0.829 |

Table 1 Dynamic performance (mean ± SD)

Static Performance

During the last 10 min. before the change of the set point were considered as steady states eFE'CO2 (= mean deviation of FE'CO2 from the set point) were used as measure of accuracy and the SD of eFE'CO2 as a measure of the stability of the control. No statistically significant difference could be found (Table 2).

| | Model-based | Fuzzy Logic | P |
|---|---|---|---|
| $eF_{E'CO2}$ | 0.013 (0.067) | -0.024 (0.205) | 0.299 |
| SD $eF_{E'CO2}$ | 0.479 (0.075) | 0.662 (0.178) | 0.144 |

Table 2. Static performance (mean ± SD)

**Conclusions**. The purpose of this study was to evaluate a new closed-loop adaptive, model-based feedback control system of mechanical ventilation using the FE'CO2 as the controlled variable and to make a comparison with a fuzzy logic control system. In order to be clinically acceptable, the closed-loop system should be safe, efficient, reliable and useful . The controller was able to regulate FECO2 appropriately. The model-based approach is able to handle different ventilation regimes and is expected to have a better artefact handling. While the previous fuzzy logic controller showed a satisfactory performance but had a very complex structure the present control design impresses for its performance and clear design, which facilitates approval by authorities.

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## Application of closed-loop ventilation in intensive care

**Haberthür C, Guttmann G***

Surgical Intensive Care Medicine, Department of Anesthesia, Kantonsspital, Luzern, Switzerland, *Section for Experimental Anesthesiology, Department of Anesthesiology and Critical Care Medicine, University of Freiburg, Freiburg, Germany

Since its introduction in the early fifties, a myriad of ventilatory modes has been introduced in intensive care medicine, which best might illustrate that we are still locking for the ideal mode for and going of mechanical ventilation. Other reasons for launching new ventilatory modes in intensive care medicine are as follows:

1) To combine the advantages of volume-targeted and pressure-targeted mechanical ventilation by simultaneously minimizing their disadvantages
2) To allow for spontaneous breathing during ventilatory support but not on the cost of dyssynchrony between the patient and the ventilator and thus not on the cost of increased work of breathing and decreased comfort for the patient.
3) To adapt the ventilatory support as close as possible to the needs of the patient, which therefore claims that the ventilatory support is automatically adapted to the ever-changing conditions of the patient i.e. clinical conditions, respiratory system's mechanics, and control of breathing.
4) To automate the process for going of the ventilator (also called weaning from mechanical ventilation).

Most of these advances are facilitated by incorporating principles of closed-loop ventilation into modern ventilators. The demand-flow principle as the basic principle of flow delivery in 3rd generation ventilators might serve as an example for a "simple" realization of closed-loop ventilation. It is at work in the continuous positive airway pressure (CPAP) and the pressure support ventilation (PSV) mode. Further examples of closed-loop ventilation that also act on a continuous (i.e. intra-breath) basis are proportional assist ventilation (PAV) and automatic tube

compensation (ATC). With PAV, the ventilatory assist is variable and synchronized with, and responsive to, the patient's respiratory effort. Furthermore, PAV selectively unloads the resistive and/or elastic portion of the patient's work of breathing. In contrast, ATC exclusively deals with the inspiratory and expiratory additional work of breathing brought on by the resistive properties of the endotracheal or tracheostomy tube. Examples of closed-loop ventilation on a breath-by-breath basis are the mandatory minute ventilation (MMV) mode and its derivatives. With these modes a minimum ventilatory target is guaranteed in the presence of (supported) spontaneous breathing. To combine constant volume delivery (an inherent feature of volume-targeted ventilation) with the advantages of pressure-targeted mechanical ventilation, a variety of ventilatory modes have been introduced using closed-loop ventilation either on a breath-by-breath or an intra-breath basis. However, the most advanced and most challenging use of closed-loop ventilation has been realized with the adaptive lung support ventilation (ASV) mode. Although working only on a breath-by-breath basis, this mode reconciles most of the demands mentioned above i.e., constant volume delivery during pressure-targeted ventilation, ventilatory support that adapts to the patient's needs, and – last but not least – the feature of automated weaning from mechanical ventilation in the vast majority of (not-difficult to wean) patients. Other solutions using closed-loop ventilation are still being developed.

## Haemodynamic assessment: Review on current non-invasive and less invasive methods

**Hofer CK**

**Institute of Anaesthesiology, Triemli City Hospital Zürich, Switzerland**

The clinical gold standard for cardiac output (CO) monitoring in critically ill patients in the intensive care unit and during anaesthesia is the invasive thermodilution technique using a pulmonary artery catheter (PAC). However, up to now, its risk-to-benefit ratio has not been determined properly. To avoid the risk of morbidity inherently associated with the PAC, a number of different non-invasive and less invasive CO monitoring systems have been developed and are available for clinical use. The purpose of this review is (1) to present these different methods and (2) to outline their practicability and limitations compared to the PAC.

### Non-invasive methods

*Transoesophageal or transtracheal Doppler ultrasound:* CO is calculated from the measured aortic blood flow and the cross-sectional aortic area, which is obtained either from nomograms or by ultrasound determination. Clinical trials demonstrated inconsistent results regarding accuracy and repeatability of these method mainly due to indispensable adjustments of the Doppler probe for signal quality[1].

*Partial carbon dioxide rebreathing:* CO is determined by the $CO_2$ elimination based on the Fick principle. Clinical trials revealed good agreement and precision as compared with the PAC, but there is only limited clinical experience. Problems arise especially from respiratory changes[2].

*Thoracic bioimpedance:* CO is assessed from changes in transthoracic electrical resistivity. Clinical trials revealed inconsistent results. Electrocautery, surgical manipulation and mechanical ventilation my lead to inaccurate readings[3].

**Less invasive methods**

*Pulse contour analysis (calibrated by transpulmonary thermodilution*): CO is determined from the area of the systolic portion of the arterial pulse waveform. Clinical trials reported accurate and reliable results. Main concerns are changes in vascular resistance requiring repeated recalibration[4].

*Pulsed dye densitometry:* CO is assessed transcutaneously by a spectrophotometer from changes in serum concentrations of intravenously injected indocyanine green. Clinical studies demonstrated inconsistent results predominantly due to failure of signal detection[5].

Selected non-invasive or less invasive CO monitoring techniques have the potential to replace the PAC in patients where informations on pulmonary artery pressure, cardiac filling pressures or mixed venous oxygen saturation are not required. However, in clinical use, the majority of these techniques are prone to errors and failures and thus still have to be classified as experimental.

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ERGÄNZEN: **Wouters P**
**Invasive methods for haemodynamic assessment**

## Electronic patient record – Physiological data archive or workflow support


**Hurrell M**

Draeger Informatics, Glasgow, United Kingdom


Computer aided anaesthetic information management systems have evolved considerably since the first true examples in the early 1980s. The first generation were essentially substitutes for the manual record which offered some benefits in terms of convenience and legibility but little else. Later systems added significant extra value by aggregating data from large numbers of individual records allowing comprehensive analyses for the purposes of clinical audit, epidemiology and quality assurance.

The next major evolution will be the development of smart systems which support clinical decision making at various levels. This can be considered as operating in three time frames.

1. Long-term retrospective analyses using techniques for knowledge discovery to assist in developing best practice guidelines and to perform epidemiological studies.
2. Case centred support which prospectively guide user choices concerning, for example, the choice of anaesthetic technique, prediction of likelihood of complications e.g. PONV and estimation of case duration.
3. Immediate intelligent feedback and guidance provided in real-time for example rule-based electronic prescribing

To support these requirements standard terminologies are needed to provide explicit and consistent encoding and to allow data derived from different institutions and countries to be aggregated. However, this is only a first level requirement. In future 'intelligent' systems will require the use of sophisticated formal ontologies expressed using a standard language and syntax. This is the essential foundation for machine inference which, amongst other things, enables interfaces that anticipate the user's requirements.

These topics are considered with reference to major current initiatives specifically the HL7 V3 RIM, SNOMED CT and OIL. Possibilities for implementations based on these are discussed together with their relevance to workflow support.

## XML and hand held computers in anaesthesia

**Gardner M**

Department of Computing Science, University of Glasgow, United Kingdom

**Introduction**. Despite a recognition that they are essential for the future progress of anaesthesia, computerised anaesthesia information management systems (AIMS) are not in widespread use. Some reasons for this are given by Gardner [5], including the following factors:

- Inadequate vertical integration (transfer of information between phases of the anaesthetic episode)
- Problems of integration with task sequences [1]
- Problems arising from conflicts between clinical and administrative record use [6]
- Limited mobility (PC based systems are unavailable or difficult to use in many clinical locations)
- Lack of workable standards (for both document structure and term vocabularies)
- Inadequate horizontal integration (exchange of information with other hospital systems, such as laboratory or pharmacy systems)
- Lack of perceived benefit to immediate users (eg lack of clinical decision support)

In the first year of the new millennium, the great majority of anaesthetic episodes will have been managed using paper-based information systems. Computerised AIMS are far from ubiquitous. This situation may change in the near future if next-generation AIMS:

- support the full extent of the anaesthetic episode, especially pre- and post-anaesthetic assessment (including post-discharge assessment)
- exploit the potential of mobile computer devices

- facilitate vertical and horizontal integration
- use appropriate standards for information exchange
- provide obvious benefits to the immediate user

Two of the most important recent developments of the last three years are the advent of XML and related standards; and advances in mobile device technologies. These two developments have very strong synergies, and could have a major impact on AIMS.

**XML in anaesthesia**

The use of a systematic structure for anaesthetic records is not new. The Casebooks of John Snow contain over 900 anaesthetic records, dating from approx 1848-1857 [3]. These records are hand-written, but demonstrate a clear if implicit structure, not dissimilar to the structure manifest in modern paper anaesthetic record forms.

Commercial computerised record systems have an underlying schema which is both detailed and explicit, but there are two problems. Firstly, such schemas are very difficult to create, and in the current business climate are quite justifiably considered to be valuable intellectual property. They are therefore proprietary, and are not revealed even to customers who purchase the systems. Secondly, these schemas are expressed using "languages" chosen because they facilitate building systems with the technology to which the commercial developer is already committed, not because they facilitate information representation and exchange. For example, the structure of an anaesthetic record can be represented, in effect, as a Relational Data Model. This approach is very convenient if one intends to build an anaesthetic information system around a Relational Database, but has major drawbacks with respect to the wider picture of anaesthetic information processing and exchange.

XML is a world standard protocol for representing information structure within a document, related to a much older standard, SGML (Standard General Markup Language). Despite its conceptual simplicity, it is powerful, versatile and very widely applicable. As a product of the World Wide Web Consortium, its development is supported by all major information technology companies.

It is difficult to overestimate the importance of XML for information processing in the next decade. There are already major national government initiatives to promote the use of XML throughout the public sector (e.g. http://www.govtalk.gov.uk/). Health information standards such as HL7 CDA will be implemented using XML[2]. General purpose technologies such as web browsers, word processors and databases will exchange data using XML. Very large scale document storage and retrieval systems based on XML are already available.

The structure of XML documents is specified by a standard known as XML Schema. We have developed a very detailed XML Schema for anaesthetic records, linked to a term lexicon. The schema covers the full extent of the anaesthetic episode, and can be used to exchange anaesthetic information between systems having different internal representation formats.

**Mobile computing devices and communications**

Computerised anaesthetic information systems are not new. Twenty-first century developers surely cannot fail to be impressed by the Cardiff Anaesthetic Record System, introduced almost fifty years ago, which supported very detailed data capture and analysis covering the full cycle of every case undertaken by every anaesthetist in the scheme [7,8]. (The computational process involved was, of course, neither digital nor indeed electronic, but mechanical). Given the power of even pocket-size devices today, some designed, literally, for child's play, we may smile on reading the final sentence of the 1954 paper: *"The preparation of the annual report comprising sixteen to*

*twenty tables, once the records for the year are complete, should occupy these machines, at the most, no more than one month."*

However, this system provided a breadth and depth of audit capability which not many modern departments of anaesthesia could match today, though every single one of them has a suite of computers with functionality unimaginable in the 1950's. In the last three years a variety of hand-held computing devices have become available. These devices have fast processors, large memories, and colour screens with pen or keyboard input. Additionally they are able to communicate with other devices and systems either by wired connections or by a variety of wireless connection modes. We have built a sophisticated prototype mobile workstation for use by anaesthetists. The workstation has an advanced interface; an XML based infrastructure; and the capability for opportunistic wireless communication with other clinical information systems. In 2001 we carried out an evaluation of this workstation for the task of pre-anaesthetic assessment, using a cross-over study comparing the system with paper-based working. The study involved real anaesthetists working with real case data. Some of the results of this evaluation will be presented at the conference. (Details of the evaluation are given in Gardner, Sage et al [4].

**Conclusions**. The combination of new AIMS components running on hand held devices, with a detailed XML Schema for anaesthetic records could have a major impact on information processing in clinical anaesthesia, in at least eight respects:

- AIMS purchase and upgrading
- Clinical decision support
- Audit
- Clinical governance
- Education and training
- Problem patient registers
- Critical incident reporting
- Research

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## Visual integration of clinical applications

**Kerker T**

Philips Medical Systems, Böblingen, Germany

Access to patient information can sometimes be very difficult, time consuming and frustrating to clinical users. Information is provided in different formats and by a variety of systems. Health care enterprises (HCE) sometimes try to address this in pushing one large system into the clinical environment that claims managing all patient information. This can be an organizational challenge, budget stressing investment and might evolve to a never-ending implementation story.

Visual Integration (VI) of information can be an approach to avoid the risky challenge of pushing a ‘one size fits all’ system into an organization. VI provides a migration path to bring clinical information, stored in distributed systems, to a common clinical desktop. Whether these are X-RAY or ECHO images, ECG or lab results, or any other kind of documents and information that is available electronically, all is shown in a single seamless view. With one click access to applications, documents and systems.

A single user logon to the VI front-end and automatic patient context switching when navigating between application and data sources makes information retrieval easy for the clinical users. User authentication is done automatically and transparently.

The information providing systems will keep the responsibility for their data in how it is created, edited and stored. With that, HCEs keep their investment in existing systems and know-how. As a web-based solution VI can be accessed at any Windows client PC running Internet Explorer with no special infrastructure needs. System management and servicing is done centrally.

VI as a Medical Applications Portal allows the introduction of a distributed Electronic Patient Record (EPR) into a HCE that can grow as needed. Even a controlled access of patients to their own data is a service that HCEs can provide to their clients.

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## Anaesthesia information management systems - Ready to sell

**Segal E, Perel A**

Department of Anesthesiology and Intensive Care, Sackler School of Medicine, Tel Aviv University, Sheba Medical Center, Israel

Anesthesia Information Management Systems (AIMS) lead to significant improvement in a number of aspects of anesthesia data recording. Vital sign recording, clinical interventions, time stamps on different events throughout anesthesia and surgery are some of the benefits during individual case management, as well as allowing the clinician more time to dedicate to the patient rather than charting. There are also significant advantages in the use of AIMS for OR management, case load, types of anesthetics and clinical performance and drug use.

One of the most important issues is that of quality assurance and risk management. To enable optimal use of AIMS, design must take into account the capacity for maximal information recording, combined with easy and intuitive user interface and strong tools for decision support and query abilities. An AIMS system (MVOR) was developed based on a commercial patient data management system for the ICU (Metavision, IMDsoft, Israel). Its unique properties are easy configuration for specific requirements, clinicians and procedures, and a sophisticated tool for decision support, a user configurable alarm, the event manager.

The presentation describes the requirements from a commercial anesthesia information system, and our experience in implementing the MVOR AIMS.