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Symposium Director: Bradley E. Smith, M.D.
Department Chairman: Charles Beattie, Ph.D., M.D.
Abstracts Editor: Darel G. Hess, Ph.D.

1. The development of a process-based database system for intensive care units

P. Laback, O. Laback
University of Technology Graz, Austria

Introduction: Database systems with a wide range of evaluation possibilities are a very actual topic. There are many spezialized database systems in use, some for billing support, some for decision-support or documentation, a few for scientific purposes, but they are mostly 'closed' systems that require their own seperated data input and present their output through printouts or screen displays. To provide a modern medical database system, a new procedure is necessary: The problems must be analysed by collecting and analysing the biomedical and physical processes to describe.

Settings: We have planned and realized the technical part of several different developments in anaesthesia and intensive care units. Therefore we have the possibility to use a wide range of self-developed data transfer drivers for various systems covering HP CAREVUE 9000, PICIS and SPACELABS systems. We have also developed a very usuable database and index structure, which we call 'causal event space'. Based on this structure it is possible to develope very clear evaluation algorithms for almost any medical expert question.

Methods: Any time we integrate the medical knowledge of an additional unit we use the same strategy:

1. Checking and updating current hard- and software ressources of the unit.
2. Collecting all present medical questions.
3. Formalizing the problems by identifying the processes on which they depend.
   Based on that the presently documented parameters are evaluated concerning causalities and measure intervals.
   In this step the PDMS documentation routine can be modified.
   For example more strict validation or shorter measure intervals can be introduced.
4. Programming or/and configuring the DIM (Data Import Module), which is responsible for transfering the PDMS (Patient Data Management System) output to the event space structure.
5. Creating a parameter discussion table to which the problems formalized in (3) are distributed.
6. Developing an EQC (Expert Question Compiler) which is the algorithmic basic for the development of the database user's front end application.

Results: There are two main results: On one hand we can deal with homogenous data of high quality. This is a good basic for standardization matters and multicentral analysis. On the other hand we collected medical expert knowledge in a format which is easily processable by computer algorithms. With every new unit containing some particular expert knowledge the EQC gets more intelligent and flexible.

2. European Consortium for Intensive Care Data

Jean-Roger Le Gall

Organization: In the Spring of 1994, the Executive Board of the European Society for Intensive Care (ESICM) voted to support the formation of a Europe-wide data collection organization to pursue the goals noted above. In the September of 1994, the European Consortium for Intensive Care Data (ECICD) held its first board meeting. The organization is governed by an independant Database Board consisting of 9 members chosen partly from the governing bodies of the ESCIM and partly from the general membership of the ESICM. This Board is responsible for the development, rules and governance of the ECICD.

There is also a 6 member Scientific Committee made up of well respected clinicians and researchers chosen for their expertise in several fields relating to Intensive Care. This committee is responsible for determining the scientific objectives of the ECICD and for approval of project requests.

The Operations/Management section of the ECICD will have capabilities in the fields of Biostatistics, Intensive Care, Quality/Outcomes Measurement, and Data Management. The ECICD will be run by professional management already managing a large ICY database and with recognized experience in the fields listed above.

In each country where that is collected, there will be a 'Country Coordinator' and one or more data managers. The Country Coordinators will work closely with the ECICD but will not be employees.

The Data Base: Initially, institutions will be asked to contribute a minimum common data set consisting of the clinical markers in SAPS II and MPM II, diagnosis, lead-time bias, procedures and interventions performed, length-of-stay information, and outcome (lived/died). It is felt that this data set will give a significant amount of information and will be very easy to collect. This, plus the quality and performance reports issued to contributing ICUs by the ECICD, will encourage units to join.

However, the system architecture is designed to be very flexible and it is expected that groups of units will choose to collect additional information that will be useful to them and to others. It is believed that the number of ICUs contributing will be large and the information ultimately in the database will go well beyond the minimal data set.

The Database already contains the detailed informations on more than 14000 intensive care patients collected in the European/North American Study.

Uses of the Database:
ICU quality and management: Subscribing ICUs will receive periodic descriptive, demographic and performance reports. These report show the relative performance of a given ICU against the norms established in the database.

Modeling: The staff will update existing severity models and will develop new statistical models related to clinical outcomes. These models will be both general models and for specific conditions. With these models, new quality measurement tools and outcome measurement systems will be developed.

Research opportunities: Probably most important, the ECICD database is designed to be a cooperative effort. Contributing institutions and researchers will have access to the database for their personal research. European pharmaceutical and equipment companies may also request reports from the database. It is expected that there will be a great demand for these services. (For more details FAX to JR LeGall 33142499425)

3. Austrian specification group for a database system for intensive care

Ph.G.H. Metnitz, P. Laback & the ASDI working group

The Austrian Specification Group for a Database System for Intensive Care [1] was founded in November 1994. Experiences made with the use and integration of Patient Data Management Systems in Intensive Care Medicine in the past years built the base of our investigations. The aim of this working group is the establishment of a database concept for Intensive Care with respect to computer-based Intensive Care documentation as a necessary future tool within the frame of quality control and scientific research [2]. Especially comparison of morbidity, mortality and outcome between different ICUSs as well as the development of multicentre study protocols need a common data structure to be easily done. The goals of the working group were defined as follows:

1. Definition of an Intensive Care Data set: With respect to the fact, that most of the ICUs in Austria are not equipped with Patient Data Management Systems and, thus, have to document manually we decided to define a 'minimal data set' (MDS) first, which will include the minimum data necessary for nationwide quality control. The MDS should content a set of parameters for measuring and comparing following items:
- demographic data;
- admission diagnoses;
- ICU scores;
- parameters to describe organ functions reflecting the course of medical treatment;
- diagnostic and therapeutic interventions;
- outcome;
- compatibility with the European Consortium for Intensive Care Data [3].

To give all Austrian ICUs a chance to fullfill required documentation – when necessary manually, automated if possible – we had to limit documentationtime to an amount of 10 minutes per patient/per day. The maximum amount of parameters to be possibly scored in this interval has to be evaluated, but may be less than wanted. Definition of the MDS needs a detailed parameter discussion with respect to different levels of abstraction, including e.g. parameter nomenclature, parameter band width, oscillation etc. The sampling rate of parameters (in the MDS mostly once daily) is as well defined as special circumstances necessary for measuring (lowest/highest value etc.). Currently our MDS includes as many as 85 parameters, which are defined and classified in around 35 different categories/fields in the so called parameter discussion table.

Communication between the different ICUs in this project is achieved over a two-step process: The central working group helds its meetings every two to four weeks. Peripheral ICUs are informed via electronic (Internet) or paper based communication afterwards. Feedbacks are welcome and integrated into the next working group meeting. After successful implementation of the MDS, a so called 'extended dat set' (EDS) is planned to be discussed. It will be a configurable enhancement of the MDS to ensure complete ICU documentation, regarding thus special attention to the possibilities of automatic documentation.

2. Realisation of the MDS in a database system: Coming from a problem-oriented approach, our database structure is based on the assumption that patient data are describing biological processes. This is done through occuring events, which together build the base of a 'process-based' database structure. The once defined MDS will be realized in a database system, using this structure. After successfull implementation, acceptance as national standard for ICU documentation should be accessed. According to the needs of ICUs without computerized documentation available, a front end application for data entry as well as for routine queries will be distributed with the database system.

3. Realization of a nationwide database: Currently we are under development of a concept for the integration of data sampled in different ICUs. The MDS applied on a single ICU is a local project, without special needs for the protection of patient data. For a nation-wide database patient data have to be encoded, without the possibility for non-authorized persons to impair patient rights by getting access to their data. Questions arise, like further

identification of patients and the possibility of data access from outside which have to be solved before the standard created can be regarded as a nationwide quality control instrument.

Notes

[1] The following members are permanently attending the group:
- Representatives from Intensive Care societies (Anaesthesiologic, Medical, Neonatal)
- ICU 13H1, Clinic of Internal Medicine IV, University of Vienna
- ICU 13B2, Dep. of Cardiothorcic and Vascularsurgical Anaesthesia, Clinic of Anaesthesia and General Intensive Care, University of Vienna
- NICU, Division of Neonatology, Clinic of Pediatrics, University of Vienna
- Medical ICU, 2nd Medical Dep., KH Rudolfstiftung, Vienna
- Dep. of Anaesthesia, UKH Meidling, Vienna
- Dep. of Anaesthesia, KH Horn, Lower Austria
- Medical ICU, 1st Medical Dep., University of Graz, Styria
- Medical ICU, Medical Dep., KH Barmherzige Brüder, Linz, Upper Austria
- Institute 501C, Graz University of Technology, Styria
- Traumatologic ICU, Clinic of Anaesthesia and general Intensive Care, University of Innsbruck, Tirol

[2] Protocoll of the constituting ASDI – session on 9th November 1994. Unpublished material.

[3] ESICM working group: European Consortium for Intensive Care Data, JR LE Gall, Paris.

4. Monitoring and therapy planning as a real-world problem: VIE-VENT

Silvia Miksch, Werner Horn, Christian Popow & Franz Paky
Austrian Research Institute for Artificial Intelligence (OFAI), Schotteng 3, A-1010 Vienna, Austria

Motivation: This work is part of the growing field of monitoring and therapy planning in medical domains. We were particularly motivated by the real-world problems of such processes facing an unexpectable high amount of faulty data and various types of data available occurring at various frequencies (e.g., high or low frequency data). Moreover, there exists no reliable structure-function model because the underlying mechanism is often poorly understood.

In contrast to diagnosis, which tries to find the best explanation for the actual situation of a patient, monitoring and therapy planning imply actions: monitoring indicates observing the course of a patient's condition under a given therapy, and assessing whether a selected therapeutic action is effective and if a predicted improvement of the patient's condition occurs. Therapy planning involves selecting of therapeutic actions which may improve the patient's condition, predicting the outcome, and adopting a therapeutic plan according to some explicitly defined preferences on the predicted condition of a patient.

VIE-VENT: a knowledge-based system for monitoring and optimizing the artificial ventilation of newborn infants: Enhanced knowledge about the mechanisms of barotrauma and oxygen toxicity and the introduction of non-invasive patient monitoring facilities helped in the development of patient-tailored strategies of mechanical ventilation thus improving survival rates and morbidity of neonatal intensive care. However, the increased demands on the medical skill and the information overload arising from the many continuously assessed physiologic variables may cause patient management problems at neonatal intensive care units (NICUs). Medical Knowledge-Based systems may help to organize knowledge, to structure information, and to help in decision making.

We developed an open-loop, real-time constrained system for optimizing the mechanical ventilation of newborn infants, called VIE-VENT. It uses quantitative on-line (like ventilator settings, transcutaneous blood gas measurements) and qualitative off-line input (like chest wall expansion, spontaneous breathing effort), and incorporates

alarming, monitoring, and therapy planning tasks within one system to overcome important limitations of existing systems.

We developed methods for data validation and therapy planning which incorporate knowledge about point and interval data, as well as expected qualitative trend descriptions to arrive at unified qualitative descriptions of parameters (temporal data abstraction). Our methods are based on data-point-transformation and curve-fitting schemata which express the dynamics of and the reactions to different degrees of parameters' abnormalities as well as on smoothing and adjustment mechanisms to keep the qualitative descriptions stable.

Therapy recommendations, based on transcutaneously and invasively determined blood gas measurements, are formulated in terms of recommended changes of the ventilator settings aiming to improve ventilation and oxygenation. The amount of a recommended change depends on various parameters such as the degree of blood gas abnormality, the course of the respiratory disease, and the chosen ventilation strategy (e.g., aggressive or slow weaning). A change of the ventilator's settings is evaluated by monitoring the trend of the subsequent changes of the transcutanous blood gases. A new recommendation is formulated if the short-term trend does not meet present requirements concerning the direction and the amount of the expected change.

The system should support the decision-making of junior and senior neonatologists by providing comprehensive monitoring data analysis and understandable therapy recommendations. VIE-VENT is currently implemented and evaluated at two different NICUs.

References

1. Miksch S, Horn W, Popow C, Paky F. VIE-VENT: Knowledge-Based Monitoring and Therapy Planning of the Artificial Ventilation of Newborn Infants, in: Andreassen S, et al., eds., *Artificial Intelligence in Medicine: Proceedings of the 4th Conference on Artificial Intelligence in Medicine Europe (AIME-93)* (IOS Press, Amsterdam, 1993) 218–229.
2. Miksch S, Horn W, Popow C, Paky F. Utilizing Temporal Data Abstraction for Data Validation and Therapy Planning, *Österreichisches Forschungsinstitut für Artificial Intelligence*, Wien, 1995; *TR-95-12*.

5. Dutch intensive care database

C.P. Stoutenbeek

In January 1994 a consortium of 11 university and teaching hospitals initiated a joined project for making the common specifications for an information system in Intensive Care and for a national intensive care database.

This project has the following objectives:

1. the making of detailed Dutch specifications using conceptual modelling.
2. clinical test of a pilot information system based on the Dutch specifications
3. the definition of a minimal common dataset for the national Intensive Care Database and the creation of an organizational structure.

As a first step the hospitals have to reach consensus on the minimal dataset. This includes the demographic data, the prognostic scoring systems, the classification systems to be used for admission diagnoses, procedures and interventions, outcome, etc. However, it is not only important to define which data should be collected but also how these items are defined and how these have to be collected. In the Dutch project it is planned that these items are automatically collected by a patient data management system as part of the care process. This increases the consistency of the collected data and decreases the number of missing values and may thus improve the quality of the data collection. The objectives of a national IC-database include:

1. *quality assessment* by comparing the outcome of patient groups having comparable prognostic scores and diagnostic groups between institutions.
2. *Technology assessment:* evaluation of Intensive Care technologies.
3. *Research tool: e.g.*, the generation of hypothesis, the design of studies and the evaluation of treatment protocols.

Each of the participating ICU's will have on-line access to the database and will have the analytic tools to produce the standard reports to assess the performance of their ICU against the norms established in the database or in specific subsets of patients.

The database will be maintained and financially supported by the participating ICU's. The database will be a very flexible system allowing specific items to be collected by a number of ICU's for a period of time for a specific project. The national database should be compatible as much as possible with the planned database of the European Society of Intensive Care Medicine and the one of the American Society of Critical Care Medicine.

The pilot Dutch Intensive Care Database should start in August 1995.

6. Quality control and audit in ICU – a minimal data set for standardized documentation

Th. Weiler, W. Heinrichs & J.E. Schmitz

Quality documentation and assurance is becoming a more and more important component of medical activity. Concerning intensive care medicine quality of treatment is particularly difficult to define because the initial conditions of ICU-patients vary extremly. Moreover, various qualities like the quality of medical treatment, the quality of the conditions under which this treatment is provided and the quality of outcome must be documented.

In cooperation with the Comission for Quality Control in Anaesthesiology of the German Society of Anaesthesiology and Intensive Care (DGAI) we present a minimal data set for standardized ICU documentation. In the presence of a general agreement that the goal of all of our intensive care efforts is the stabilisation and rehabilitation of essential vital functions as well as the protection against any threatening danger, this data set is orientated first on the organ functions and secondly on a special therapy of the basic disease. Organ dysfunction has to be classified according to the degree of severity and to the temporal course of the treatment. To define the initial status of the patient SAPS II [1] is included into the data set.

We categorized our ICU-documentation according to 5 different groups:
Group I : Administrative data
Group II : Reasons for administration. Estimation of risk (SAPS II)
Group II : ICU course documentation
Group IV: Data on time and measure performed
Group V : Data on the status after ICU treatment (Outcome)

The determination of documentation contents should be based on the assumption that intensive care medicine deserving this name has to fulfil minimum diagnostic and therapeutical requirements. We consider one of these that an intensive care patient should undergo a complete physical examination, as well as assessment and documentation of individual organ functions including the overall status, at least once a day. We are aware that the indicated systematic procedure in recording and documenting the findings alone represents a specific quality standard in itself and may be expected to result in an improvement of the quality of intensive care therapy. Currently a multi center study for the evaluation of the minimal data set is performed. Results will be presented.

References

1. 1. Le Gall JR et al. 1993; JAMA 270: 2957–2963