Computer assisted data analysis in intensive care: the ICDEV project – development of a scientific database system for intensive care *

(Intensive Care Data Evaluation Project)

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Abstract

Introduction: Patient Data Management Systems (PDMS) for ICUs collect, present and store clinical data. Various intentions make analysis of those digitally stored data desirable, such as quality control or scientific purposes. The aim of the Intensive Care Data Evaluation project (ICDEV), was to provide a database tool for the analysis of data recorded at various ICUs at the University Clinics of Vienna. **Settings:** General Hospital of Vienna, with two different PDMSs used: CareVue 9000 (Hewlett Packard, Andover, USA) at two ICUs (one medical ICU and one neonatal ICU) and PICIS Chart+ (PICIS, Paris, France) at one Cardiothoracic ICU. **Concept and methods:** Clinically oriented analysis of the data collected in a PDMS at an ICU was the beginning of the development. After defining the database structure we established a client-server based database system under Microsoft Windows NI™ and developed a user friendly data quering application using Microsoft Visual C++™ and Visual Basic™; **Results:** ICDEV was successfully installed at three different ICUs, adjustment to the different PDMS configurations were done within a few days. The database structure developed by us enables a powerful query concept representing an 'EXPERT QUESTION COMPILER' which may help to answer almost any clinical questions. Several program modules facilitate queries at the patient, group and unit level. Results from ICDEV-queries are automatically transferred to Microsoft Excel™ for display (in form of configurable tables and graphs) and further processing. **Conclusions:** The ICDEV concept is configurable for adjustment to different intensive care information systems and can be used to support computerized quality control. However, as long as there exists no sufficient artifact recognition or data validation software for automatically recorded patient data, the reliability of these data and their usage for computer assisted quality control remain unclear and should be further studied.

1. Introduction

Intensive Care Units (ICUs) are increasingly confronted with incredibly large amounts of data originating from diagnostic and therapeutic devices as well as from clinical documentation. Modern computer technology allows the handling of such data masses in Patient Data Management Systems (PDMS) which are designed to substitute the patients documentation on paper sheets by comprehensively structurize digitally stored data. These systems are specialized to collect, visualize and store clinical data such as demographics, vital parameters, doctors and nurses plans and notes and to facilitate complex calculations for input-output balances, hemodynamic parameters and clinical scores [1]. Until now, the main focus of a PDMS was to represent a patient's data on computer screens at the bedside and printouts.

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Less attention has been paid, however, to computer aided data analysis although there is a need of clinical information.

Critical care is increasingly provided to severely ill patients. Rapidly increasing costs put a pressure on cost control and effective utilization of resources [2]. Bedside based computer systems may reduce operating efforts and costs [3–5], at least by collecting service-related data which are the base for effective cost control programs. Documentation and analysing of individual intensive care data is, however, realistically possible only with the aid of computers [6]. PDMS facilitate automatic recording of patient data sampled from peripheral devices (such as monitors, ventilators, etc.) in defined intervals and provide thus an almost continuous overview of vital parameters, depending on the sampling rate of the system [7]. These data can then be displayed or may, for example, be used for calculating functional indices. Scoring systems, e.g., are increasingly used for audit at critical care units [6, 8]. Manual data retrieving and handling being very time-consuming, restrictis audit programs for ICUs still within narrow limits: because preparation of manually generated audit reports may take up a few months [2], necessary measures may come too late. Electronic analysis of clinical patient data could allow retrospective examination of concepts and provide a basis for the implementation of necessary measures [9–11]. The availability of continuously recorded patient data in a PDMS would render superfluous the extremely time-consuming manual analysis of printed or written data sheets and provide an optimal base for computerized audit programs [2].

Some authors see the justification of a PDMS to work as a decision-support tool in complex situations within the ICU [12]. The main function of an expert system lies in helping to make decisions, based on interpretation of available data from various sources. As an integrative element, a PDMS should be able to supply the appropriate data set [13, 14]. Moreover, continuously recorded data, stored in a scientific clinical database, including diagnoses and treatment would represent a powerful tool for the development of new expert systems or for the validation of existing ones [15].

Although these arguments point out the necessity of the integration of an analysing system within a PDMS, vendor's announcements have never reached clinical applicability. As far as we know, only few ICUs in Europe are currently able to process their PDMS data further for quality management and cost accounting

(Kuopio University Hospital, Finland, PDMS: Clinisoft). We therefore developed a general data storage and analysis system for ICUs, the Intensive Care Data Evaluation System (ICDEV). It is based on a specially developed data model, implemented in the relational database SQL Server NT™ (Microsoft Corp.) and includes facilities for data import, storage and retrieval as well as user friendly features for patient or patient group based data analysis. The aim of this study was to describe and to test the functionalities of ICDEV for importing, storing and analysing data from two different PDMSs for ICUs, Care Vue 9000 (Hewlett Packard, Andover, USA) and PICIS Chart+ (PICIS, Paris, France).

2. Settings

The General Hospital of Vienna (AKH, Vienna) has thirteen ICUs (two medical, a neonatologic, one coronary care, an acute dialysis, a burn unit, three anesthesiologic, two surgical, a neurosurgical and a transplant ICU) equipped with the Hewlett Packard CareVue 9000 Patient Data Management System and one cardiothoracic ICU equipped with the PICIS Chart+. Both systems are different in respect to their system design and database interface.

2.1 Hewlett Packard CareVue System 9000

The PDMS Care Vue 9000, software release F.0, is presently installed at various ICUs of the General Hospital, Vienna, on Hewlett Packard Apollo 700 workstations. The program runs under the operating system HP-UX 9.0 and records up to 2000 different patient related variables which are entered manually (e.g. nursing care parameters) or recorded automatically (e.g. from patient monitors or ventilators) at intervals ranging from 15 minutes to three hours. The patients' data are stored in an Allbase™ database and are online available at the bedside as long as a patient is admitted to the ICU. Because the system at present has no long term archiving capabilities, patient data are automatically deleted approximately 30 days after discharge with the delay depending on the amount of data stored in the database. Long term data storage is organised using daily printouts. Selected data may be exported from the database to a PC in ASCII [16] text format using the DBExport™ (Hewlett Packard, Andover, USA) software. Further data processing, however, is currently not supported.

2.2 PICIS Chart+

The PICIS System is presently running at the cardiothoracic-anesthesiologic ICU on a network of PCs equipped with Intel Pentium processors. The program runs under the operating system Microsoft Windows™ or Windows NT™ (Microsoft Corp.) and consists of various program modules like PICIS Chart+™ for online data sampling and handling and PICIS Care Manager™ for care management. Data are sampled online from various devices (like patient monitors or ventilators) at intervals of 10 seconds or more depending on the data output of the peripheral devices. The data are locally stored as one minute mean values. These mean values are then transferred after a configurable time interval (e.g. ten minutes) to a server PC where they are archived in ASCII files, again as mean values. Long term data storage and data export are organised using standard file handling capabilities of the operating system. Demographic and nursing data are recorded manually and are stored in a separate database (Microsoft Access™). The PICIS Care Manager™ application is presently being implemented, so care procedures up to now are not recorded in the PDMS.

3. Concept and development of the ICDEV Database System

3.1 Conception of a Scientific Database System

Consideration of the most important clinical questions arising at an ICU was the beginning of the database development. Already here, a systematization of the PDMS data to be evaluated forms the necessary basis for informatic realizability [17]. Therefore the functions of the database have first to be defined: documentation, scientific analysis, cost accounting, etc. Next, necessary parameters must be selected and classified. The *Output* of the PDMS has to be analysed for its functionality as an *Input* for the evaluation system, to determine, if the PDMS *Input*, and thus the PDMS-configuration has to be modified:

- definition of the data sampling interval: does a defined parameter represent an instantaneous record of a continuous process (e.g. of a running infusion) or is it a particular event (e.g. an acute intervention)?
- data validation: should automatically recorded parameters be manually validated, are all existing

values equally important? This is important, when a representative value for a defined time interval has to be choosen (e.g. to compute scores) or for defining suitable parameters for clinical studies.
- formatting guidelines: standardization of the PDMS *Output* using appropriate data entry methods such as selection lists for manual text input, formatting recommendations for date fields, etc.

Medical questions involve complex descriptions of biological processes. It is of essential importance that a range as great as possible, of processes available, be considered for the definition of a highly qualitative database system. Description of an organ failure is e.g. an example for a biological process, the reaction of an organism to an applied therapy another. Appropriate knowledge of the course of the biological process is necessary for realizing an appropriate time correlation concept. Secondary information must be collected from various areas of knowledge (e.g. time analysis, bio processing, etc.). Building upon this, we developed a database structure which we call the CAUSAL EVENT SPACE MODEL. It consists of a list of all documented events and a special index structure, making the *Output* of the PDMS available at different levels: at a single patient and a patient group level, for time-analytical considerations as well as for multivariate analysis.

3.2 Development of the Data Import Module (DIM)

The *Output* of both PDMSs, CareVue and PICIS, is available in form of raw ASCII files. To use these as *Input* for the clinical data evaluation system, we had to develop a DATA IMPORT MODULE. It consists of a set of various data transfer algorithms with the primary function of transformatting the acquired text elements into elements of the CAUSAL EVENT SPACE MODEL. As the structure of the ASCII files is different from system to system, a specific DIM driver is needed for every PDMS. At present, we have implemented drivers for the HP CareVue 9000 and the PICIS Chart+ systems, drivers for SpaceLabs and Hellige systems will follow.

Regular and automated data import from the PDMS must be failure proof. A failure of the data import process will invariably result in an incomplete data set because most PDMSs have no long term archiving functions. Therefore the consistency of the database depends essentially on the reliability of the DIM. Since the data exported from the PDMS are in ASCII format,

Table 1. Patient data categories exported from HP CareVue and PICIS Chart+.

Patient Data Management System	HP CareVue System 9000	PICIS Chart +
Demographic data	✓	✓
Vital parameters	✓	✓
Ventilator data	✓	✓
Laboratory data	in preparation	✓
Blood gas lab data	✓	✓
Other peripheral devices data	✓	✓
Computed data (scores, hemodynamics, etc.)	✓	✓
Medication data	✓	✓
Balance data	✓	✓
Nursing data	✓	planned
Diagnostic/therapeutic interventions	✓	✓
Events, emergencies, etc.	✓	✓

erronic data have to be detected and redundant data have to be filtered out by the DIM in order to ensure a correct data transfer into the ICDEV database. Our main concern was therefore to develop safe data transfer algorithms especially through low level programming.

3.3 Hardware and software resources

Handling and performance of a large medical database application largely depends on computer performance, storage capability, and an operating system enabling multitasking and networking as well as inbuilt security and backup facilities. We implemented ICDEV on PCs equipped with Intel Pentium or 486 processors and a harddisk with at least 1 GB storage capacity, as we calculated that a disk capacity of about 400 MB per year would be necessary for the data collected at an eight bed ICU. We chose MS WindowsNT™ (Microsoft Corp.) as operating system because it offers high performance (32-bit technology), a user friendly interface with multitasking architecture, inbuilt networking and backup facilities as well as sophisticated security features.

Dealing with medical data asks for a high level of security of the operating and the database system. According to Pangalos [18], the information stored in medical databases must be secured with respect to *confidentiality, integrity and availability* [19, 20]. The US National Computer Security Center defines and evaluates security standards for operating systems, such as the C2-standard, which is recommended for com-

puter systems operating in governmental and health care areas [21, 22]. The operating system used in our project (Microsoft Windows NT™) is currently evaluated for C2-certification [23]. Both, the operating and the database server system offer most advanced security features, including multi-level password locking and transaction logging, thus preventing unauthorized access as far as possible.

The data extracted from the PDMS had to be stored in a separate (so called 'off line') database because data analysis should not interfere with routine PDMS operation. For this purpose, we chose the MS SQL Server™ (Microsoft Corp.), a professional SQL [24] database system with user friendly client-server architecture which allows for a dynamic device handling (adjustment of the size of the database according to the user's needs) even during runtime. The front end application for data quering was developed using MS Visual C++™ and MS Visual Basic™ software development kits. Both allow for easy and economical programming and provide a safe basis for the further development of the user interface.

3.4 Automatization of the export/import process

Data export from the PDMS and data import into the scientific database system must be performed regularily and automatically. Especially at ICUs, it is impossible to let computerized processes operate manually, because ongoing medical activity will frequently lead to neglecting computer operations. Missing data
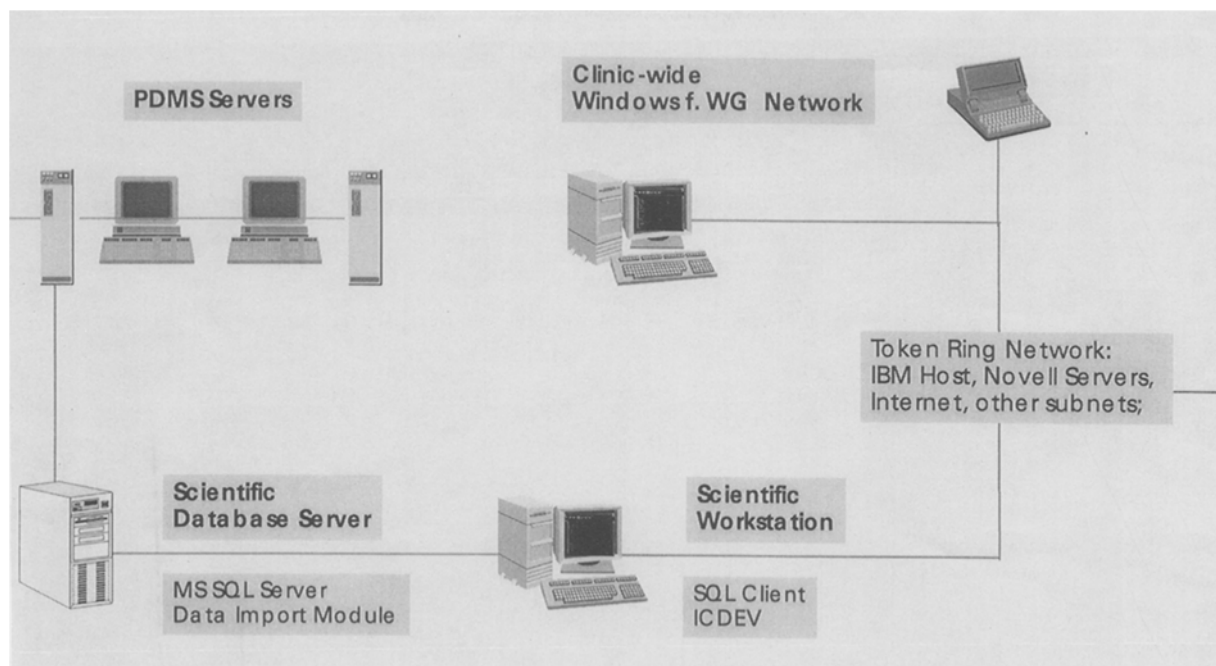
Fig. 1. Hard- and Software configuration as presently used in the ICDEV project: Scientific Database Server System (Pentium PCI-PC/Operating System: Microsoft Windows NT™), connected to the PDMS and the scientific workstation (486 VESA LocalBus-PC/Operating System: Microsoft Windows NT), which is itself connected to the hospital network. The Scientific Workstation acts as a gateway to the hospital network: no unauthorized database access is possible from outside the unit. Data from the Scientific Database Server may be redirected to the hospital network, e.g. to a clinical information system.

Table 2. Resources used for the ICDEV project.

Hard- and Software used	
Database server: hardware	Pentium PCI-PC 60 MHz, 32 MB Ram, 1 GB SCSI Harddisk, Adaptec SCSI Controller, 4 mm Dat drive
Database server: operating system	Microsoft Windows NT Version 3.1 and higher
Clients: hardware	i486 or Pentium CPUs
Clients: Operating System	Microsoft DOS 5.0 or higher, Microsoft Windows for Workgroups 3.11
Network	Ethernet (local), Token Ring (Hospital-wide)
Network protocols	TCP/IP, NetBEUI
Database system	Microsoft SQL Server 4.21
Archiving	4 mm DAT drive, NT Backup Software
Applications programming environment	Microsoft Visual C++, Microsoft Visual Basic

export, however, will result in data gaps of the external database system because there are no archiving functions integrated e.g. in the HP CareVue system. Automated safety measures must therefore be built in, in order to prevent data losses. The raw data (ASCII files) are regularly stored on optical media, the database is backed up additionally on a digital tape streamer. The described trias: data export-DIM-database server system must, for stability purposes, operate on a separate server PC, equipped with an Uninterruptable Power Supply (UPS). The necessary servicing work for maintaining the ICDEV database was reduced to
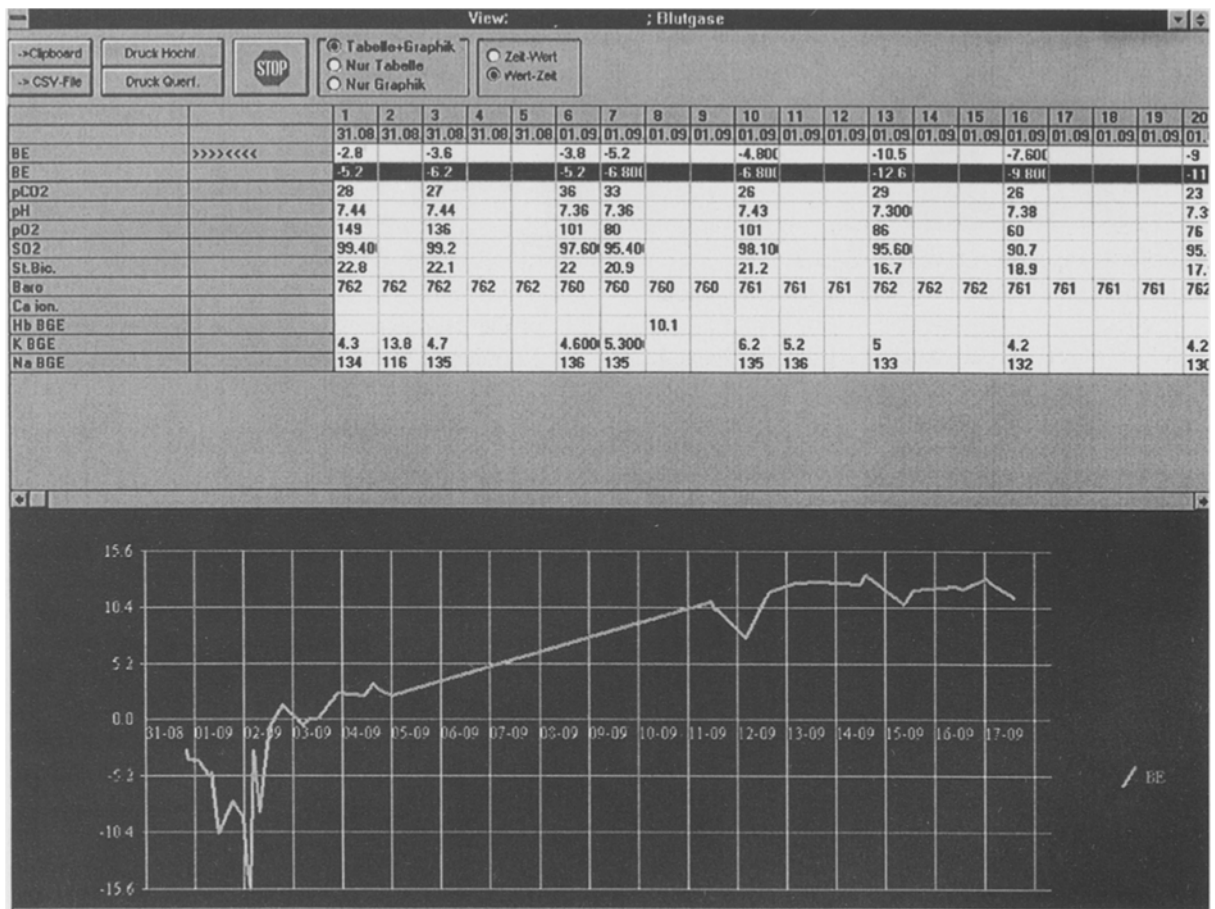
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		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
		31.08	31.08	31.08	31.08	31.08	01.09	01.09	01.09	01.09	01.09	01.09	01.09	01.09	01.09	01.09	01.09	01.09	01.09	01.09	01.
BE	>>>><<<<	-2.8		-3.6			-3.8	-5.2			-4.800			-10.5			-7.600				-9
BE		-5.2		-6.2			-5.2	-6.800			-6.800			-12.6			-9.800				-11
pCO2		28		27			36	33			26			29			26				23
pH		7.44		7.44			7.36	7.36			7.43			7.300			7.38				7.3
pO2		149		136			101	80			101			86			60				76
SO2		99.40		99.2			97.60	95.40			98.10			95.60			90.7				95.
St.Bic.		22.8		22.1			22	20.9			21.2			16.7			18.9				17.
Baro		762	762	762	762	762	760	760	760	760	761	761	761	762	762	762	761	761	761	761	762
Ca ion.																					
Hb BGE									10.1												
K BGE		4.3	13.8	4.7			4.600	5.300			6.2	5.2		5			4.2				4.2
Na BGE		134	116	135			136	135			135	136		133			132				130

15.6
10.4
5.2
0.0
-5.2
-10.4
-15.6

31-08 01-09 02-09 03-09 04-09 05-09 06-09 07-09 08-09 09-09 10-09 11-09 12-09 13-09 14-09 15-09 16-09 17-09

/ BE

Fig. 2. Example of a query at the patient level: the trend graph display shows base excess values before, during and after rescucitation of a 62 year old patient following admission to the ICU after aorto-coronary bypass operation,

a minimum through integrating tools for the database administration in our frontend application.

3.5 Development of a query program

Data records stored within the framework of the scientific database system are organized within various tables which are interconnected through a relational link structure. In addition, our data model integrates several levels of identification (e.g. patient ID, parameter ID, time stamp ID, value ID, flags), which must be combined in order to form a query. Data querying using SQL is possible for experienced specialists, which are normally not available at ICUs. Therefore, a user friendly front end tool had to be integrated into ICDEV. Usability of the query module depends essentially on the implementation of the questions discussed

in the concept phase, together with their clinical validation. The CAUSAL EVENT SPACE DATA MODEL enables a query concept which provides the possibility of compiling almost any relevant clinical question into a processable query.

4. ICDEV query tool: the expert question compiler

In order to retrieve data, queries scan the database at various levels: e.g. for hemodynamic data, the database must be scanned for a patient's ID, and for the defined cardiovascular parameters (e.g. CO, SVR, etc.). Thereafter, the defined time-interval must be searched for corresponding values which then must be put together into a table. Such retrival of data from the database is

a dynamic process, the table presenting the results is called a 'View'. To define a 'View' the user has to:

- define the type of the query; examples for different types of queries are:
  - parameter-time tables: e.g. a table with hemodynamic values;
  - counting statistics: how many arterial lines were inserted, or how often was a diagnostic/therapeutic intervention done?
  - intervals: for how long was the patient ventilated?
- select a set of parameters, e.g. hemodynamic parameters: CO, SVR, PCWP, etc.
- specify certain conditions: for example, time resolution for the data display or counting intervals for cumulative statistics.

These, parameter-specific, definitions are then 'compiled' using SQL code to form queries, which may be started by acitivating a button or may be run automatically from a scheduler. This user friendly concept of setting up queries without specified SQL or programming knowledge has been named the 'EXPERT QUESTION COMPILER', due to the 'compilation' which occurs between the pre-implemented SQL-query code and the user defined parameter specifications. This should point out the need of well defined and discussed expert questions, which are, as already claimed, descriptions of the processes to be analysed. Data queried thus with ICDEV are automatically transferred to Microsoft Exel™ workbooks and formatted appropriately with user-configurable macros into tables or graphs. From here the data may be printed out, stored, or transferred to any other MS DOS™ or Microsoft Windows™ application. This gives the possibility to visualize a patient's course at the ICU through displaying a trend graph of virtually any documented parameter over the length of the patient's stay.

Presentation of a single patient's data has the functionality of an electronically archived patient history. Although there is a possibility of filtering the data within the framework of the DIM, at present all medical and nursing data are imported into the database. Thus there is an electronic record available even after patient discharge. This partially substitutes for the missing archiving component of the CareVue system. For PICIS Chart+, the ICDEV database integrates recorded clinical with demographic and status data. Evaluation and display of treatment and care procedures facilitates patient- and service-oriented discharge statistics. An automated report will, in the near future, substitute for the manual recording of health care statis-

tics at ICUs equipped with ICDEV and is planned to be used for cost accounting and billing.

Another module of the ICDEV program supports evaluation of patient data at the unit level. Other than the patient-related evaluation which is based on parameter-time- or interval-related queries, unit-related evaluation is mainly based on event-counting and calculation of means. Such analyses can be used for two purposes:

- Service and cost accounting: Intensive care is one of the most expensive fields of modern medicine. In order to utilize available resources efficiently, a continuous cost analysis is mandatory [3]. This involves data such as admission diagnoses, length of a patient's stay, cumulated medication costs, use of expensive donor blood products or costly therapies, which can be evaluated with the use of ICDEV.
- Quality control and audit in the sense of comparing medically relevant data such as mortality and outcome, or daily assessment of severity scores. Data recorded in a PDMS can easily be used for quality management purposes.

ICDEV can work as an automated control and audit program which provides the necessary information. Queries, once defined, can be scheduled to run automatically (e.g. monthly or annual report) and the output may also be transferred to a hospital information system.

Queries relating to user-specified patient groups are used for documenting clinical studies. A patient group which is selected according to defineable criteria, can be classified into subgroups by defining additional conditions. A study table can then be composed and further processed by adding a time axis for studying time dependent changes of clinical variables. This table may be updated daily within the framework of prospective studies and an overview of the latest state of a study may be obtained without an additional effort at any time. It is also possible to create such study protocols for any, even retrospective data e.g. for determining the minimal number of patients needed for a clinical trial.

5. Results

ICDEV was first installed at a medical ICU of the General Hospital Vienna in June 1994 and at the Neonatal ICU in December 1994, both units working with HP CareVue 9000. Since April 1995 ICDEV is also imple-
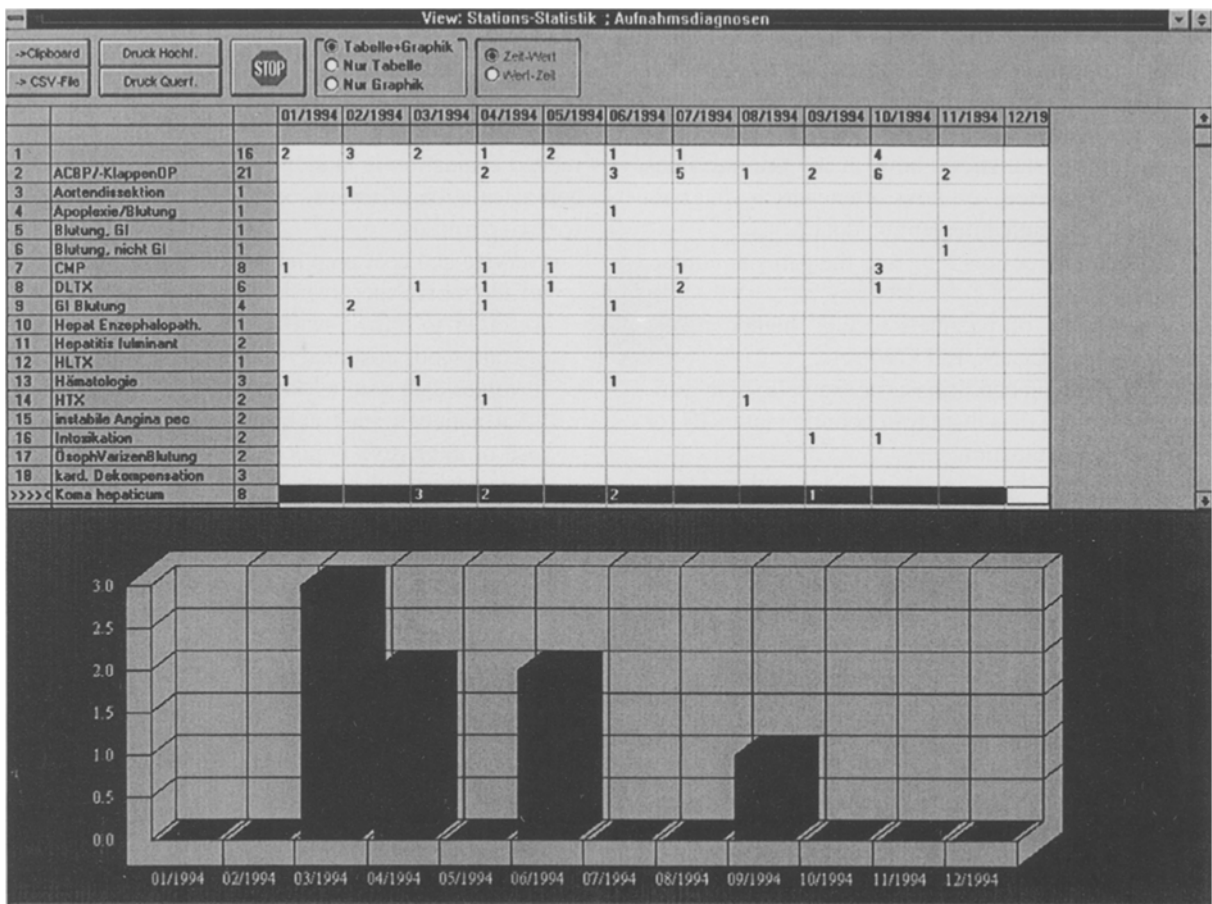
View: Stations-Statistik ; Aufnahmsdiagnosen

->Clipboard Druck Hochf. STOP ⊙ Tabelle+Graphik / ○ Nur Tabelle / ○ Nur Graphik ⊙ Zeit-Wert / ○ Wert-Zeit
-> CSV-File Druck Quert.

			01/1994	02/1994	03/1994	04/1994	05/1994	06/1994	07/1994	08/1994	09/1994	10/1994	11/1994	12/19
1		16	2	3	2	1	2	1	1			4		
2	ACBP/-KlappenOP	21				2		3	5	1	2	6	2	
3	Aortendissektion	1		1										
4	Apoplexie/Blutung	1						1						
5	Blutung, GI	1											1	
6	Blutung, nicht GI	1											1	
7	CMP	8	1			1	1	1	1			3		
8	DLTX	6			1	1	1		2			1		
9	GI Blutung	4		2		1		1						
10	Hepat. Enzephalopath.	1												
11	Hepatitis fulminant	2												
12	HLTX	1		1										
13	Hämatologie	3	1			1		1						
14	HTX	2				1				1				
15	instabile Angina pec	2												
16	Intoxikation	2									1	1		
17	ÖsophVarizenBlutung	2												
18	kard. Dekompensation	3												
>>>>	Koma hepaticum	8			3		2		2			1		

Fig. 3. Example of a query at the unit level: admission diagnoses at a medical ICU. The bars show the number of patients admitted to the ICU with the admission diagnosis of hepatic coma. Once such a query is set up it can be run at any time. To query the data of a whole year, ICDEV needed about 20 seconds running on a 60 MHz Pentium PC under Windows NT. This sets new limits for unit audits, compared with manual report preparation.

Table 3. Online data from peripheral devices, transferred into the HP CareVue and PICIS Chart+.

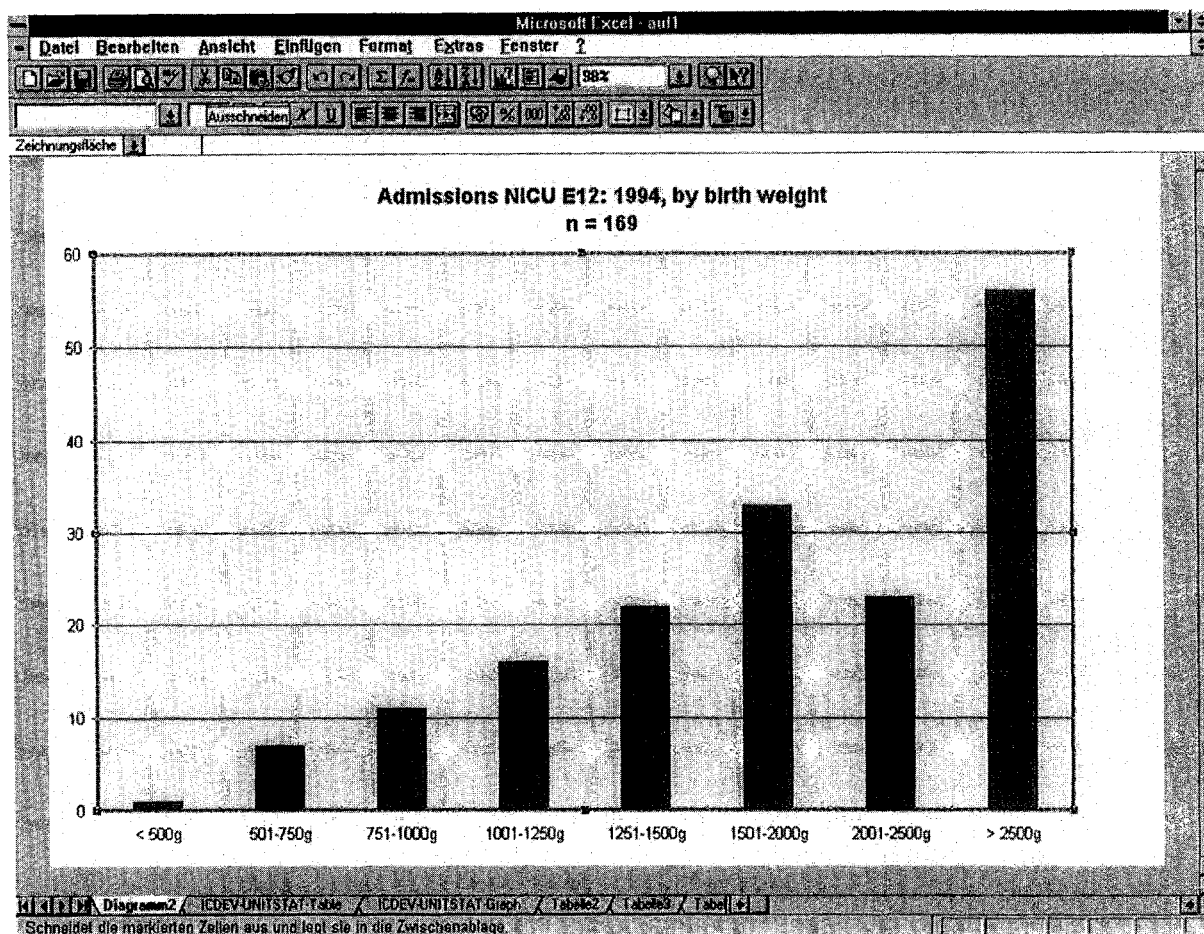| Patient Data Management System	HP CareVue System 9000	PICIS Chart +
Monitors	✓	✓
Ventilators	✓	✓
Clinical lab system	in preparation	✓
Blood gas analyser	✓	✓
IV pumps		
Continuous cardiac output monitor	✓	✓
Extracorporal therapy circuits	✓	

Fig. 4. Results of a query at the unit-level: the graph shows the 1994 NICU admission statistics. The data were queried using ICDEV and automatically exported to MS Excel where the birthweight class percentages were calculated. This is part of the annuary routine report, which is currently set up at the Neonatal ICU.

mented at the Cardiothoracic ICU, which uses PICIS Chart+ as an intensive care information system. Further installations in the General Hospital of Vienna are already scheduled. Since patient data were already collected before implementing ICDEV, data sets of one to two years of discharged patients already existed and were also imported. Actual data transfer and import into the CAUSAL EVENT SPACE MODEL is now automatically scheduled to be done daily. The database system as well as the data transfer algorithms work stable at all installation sites. However, the integration of the operating system into existing environments (local networks, existing databases) and the adaption to local needs may be quite difficult and need the help of professional engineers. The EXPERT QUESTION COMPILER was judged to be user friendly and practicable.

As the acceptance, however, of such an evaluation system raises and falls with the user friendliness of the human-machine interface, we will try to evaluate the need of our users and to adapt the application further to their needs.

The imported preexisting data sets were found to be partially faulty because of configuration and export errors. Loss of information and ambiguous data sets occurred due to configuration errors of the PDMS installation, which e.g. produced split up fields, faulty or forgotten endpoints etc. (see also chapter 6). Problems with the data export occurred because of not well defined and documented database interfaces. All these problems were problems of the PDMS and not of ICDEV. We however tried to overcome some of these
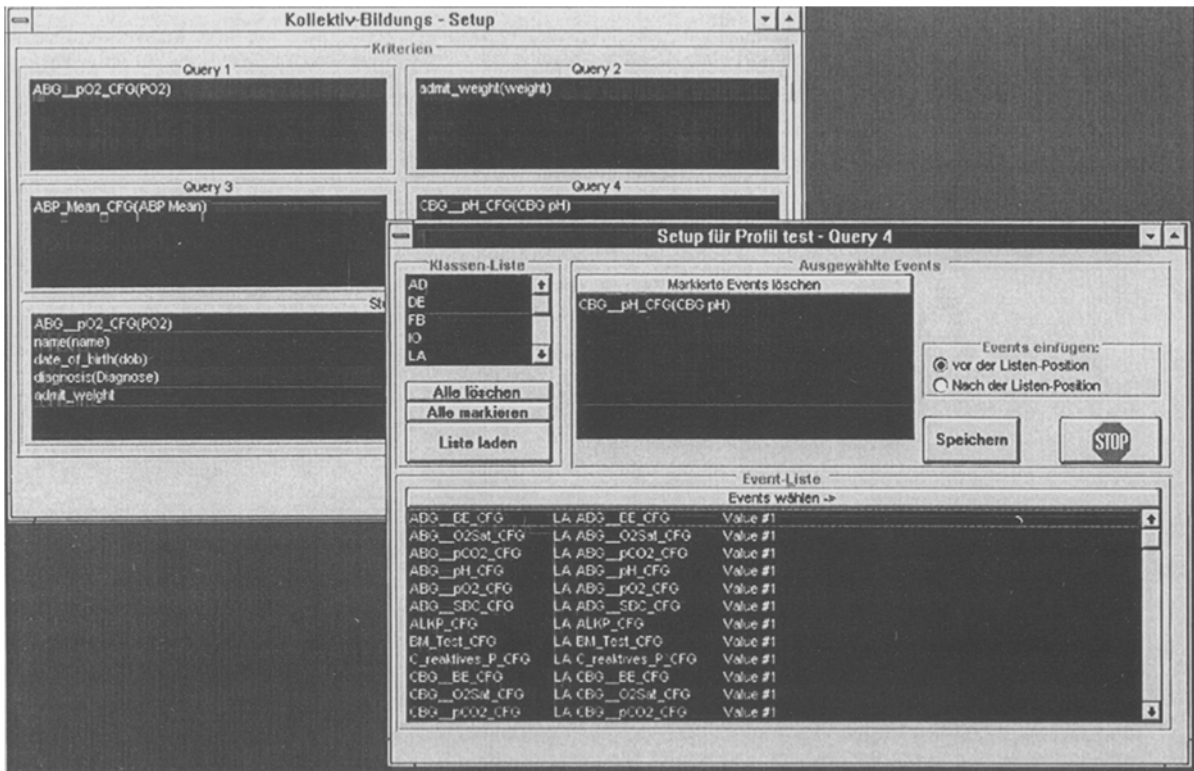
Fig. 5. A screendump showing the definition of a parameter set for building a patient collective using the Expert Question Compiler: the lower display shows a list of selectable parameters. Once selected, additional conditions, may be defined. Data of a thus selected patient group may be used for documentation and decision support of clinical studies.

problems by implementing sophisticated data validation procedures in our DIM.

6. Database quality and critical care research

Information flow within ICDEV can be classified as *Input, Throughput* and *Output* [25]. The *Input* (equal to the PDMS *Output*) is filtered and imported by the DIM. The *Throughput* consists of a collection of algorithms for compiling the expert questions and distributing the problems on processable database queries, and is supported by the index structure of the database. As a result, the *Output* is available to the user. Since this *Output* can again be used as an *Input* for another processing system (e.g. cross tabulation, statistical

or graphical applications), a whole chain of information flow may be generated where the previous *Output* serves as an *Input* for the following system. Information chains are abundant in modern hospitals because patient records are usually documented within various computer systems. Since increasing network connectivity is about to connect most 'stand-alone' systems, data transfer procedures and information chaining become more and more important.

However, not all the information that suffices as *Input* for simple paper-print-outs can easily be processed by a database system. Insufficient or missing validation of data input to a PDMS leads to various problems. If the input to text fields is free text, data records are generated which can be printed out, but usually, cannot be further processed. As mentioned above,

the admission diagnosis of a patient has to be entered into the census sheet. If the entry is made using a menu-controlled selection list, only one corresponding entry is possible. In case of free-text entry, assuming the diagnoses have been typed in correctly, a database search could reveal various entries: liver failure, acute liver failure, liver necrosis, coma hepaticum, etc. Normally, query programs will distinguish between: 'liver failure' and 'lifer failure', thus any wrong typed diagnosis would appear within a separate field and therefore be missed during analysis. Since this is valid for each diagnosis entered, in the worst case just as many diagnoses as patients could exist in the database – a situation which makes the interpretation of patient data with respect to admission diagnosis very difficult or even impossible.

In the CareVue as well as in the PICIS Chart+ system it is possible to enter free text into different fields, consisting of any ASCII character. Analysis of these data is limited to some amount, since erroneous data records are filtered out by the DATA IMPORT MODULE and are therefore missing in the ICDEV database. One of the greatest challenges for clinical databases is, however, the input of highly qualitative patient data by so-called primary data generators, that is, physicians, nurses and other health care personnel [26]. Validation of the input data using default field formats, entry limits and selection lists willl improve the quality of the database, which is an important condition for a good interpretation.

Since data are automatically recorded from peripheral apparatus, the amount of data stored in PDMSs has exponentially increased. The question of data quality applies also to these online transferred data. The two PDMSs used in our project, sampled online data at different intervals: CareVue 9000 Release F.0 has a minimal sampling interval of 15 min (at ICUs), values are represented as actual values. PICIS Chart+ samples data from 10 seconds up, depending on the peripheral devices and the configuration of the interfaces. Data are displayed as 1 or 10 minute mean values [27]. Available PDMS are not equipped with the ability to recognize artefacts (a flushed line) or wrong measurements (a damped curve), although computer aided expert systems for artifact recognition and automatic data validation are under development [15]. Therefore the quality of automatically recorded and stored data points (actual values or means) remains questionnable. Friesdorf et al. showed that less than 85% of invasively measured blood pressure values were reliable at the time of assessment, similar results were seen for other

monitoring data [28]. Thus, in our experience, data recorded without validation can (at present) hardly be used for automated calculations (e.g. finding the lowest blood pressure of a 24 hours interval for computing the APACHE II score). Manual validation of these data will still be necessary until better artifact recognition algorithms are developed. At one of the ICUs participating in this project, data validation is performed every morning shift for all automatically recorded vital parameters from all patients. Values, recognized as artifacts (e.g. typically recorded blood pressure values showing: 220/0/180 mmHg[SAP/MAP/DAP]) are deleted. Since the PDMS in this unit is equipped with an application for automatic calculation of APACHE II and SAPS II scores (from these data), missing data validation will result in wrongly calculated scores.

With ICDEV it is possible to check the consistency and quality of an existing database. Therefore, data recorded can be examined for their usefulness in answering the desired questions. Reviewing data collected since 1993, we found systematic configuration erros at various ICUs.

- data series configured in the PDMS did not have defined end-points: the definition of the endpoint of 'ventilation' is required for finding the number of days on mechanical ventilation per patient or unit.
- even if data entry stopped, services which were not marked as 'terminated' were continued to be counted in the analysis: e.g. 40 days of hemodialysis.
- services carried out over several days (catheters, hemofiltration, etc.) were often erroneously numbered by hand, since no 'counter' is provided within the PDMS.
- some services were just configured more than once (under different names and displays) and different data were entered into these, separate fields.

These configuration errors led to problems in the preparation of patient-related statistical calculations. Naturally, questions to be answered by automatically analysis are only as valid as the contents of the database. It is therefore essential that,

- the database structure reflects as much clinical reality as possible [15].
- not the amount, but the quality of stored data in terms of validity, reliability and utility have to be determined since they define the usefulness of a clinical database.

Kahn eloquently expresses what otherwise may result from interpretation attempts:

'. . . garbage in, gospel out, which highlights the tendency to accept nicely formatted computer-generated reports composed of unreliable numbers. Bad data often are aggregated into arithmetic means and changed into rates by dividing by questionable denominators and then compared to similar inferior data from prior month, quarters, or years. Decision makers rarely question the quality of the primary data from which these abstractions were generated.' [26]

Reconfiguration of the PDMS is always a time consuming and cost intensive process, which could be eliminated through sufficient planning before installation and implementation of an PDMS. Database interfaces available today are neither practicable nor reliable. In fact, database interfaces, which are able to transmit consistent data are an ultimate prerequisite of a good analysing system. Cooperation with the system developers is mandatory to overcome these problems. Artifact recognition and error handling are further issues which should be addressed by PDMS designers in order to produce highly qualitative clinical databases with data that can seriously be used for automated, computer assisted quality control assessments.

While implementing ICDEV we realized that there is a need for standardizing the contents of clinical databases for intensive care in order to facilitate data handling and database installation as well as to provide possibilities for multicenter analyses. First steps in the direction of a standardized intensive care documentation have already been made in Germany [29]. In order to support the standardization idea in Austria, we founded a working group (ASDI: Austrian Working group for Standardisation of a Database System for Intensive Care) in October 1994. The aim of this working group is to establish a database concept with respect to computer-based intensive care documentation as a multiusable tool for quality control and scientific research [30] and to participate in international projects achieving consensus in intensive care documentation for quality control [31].

From the beginning, the ICDEV concept was made as individually configurable as possible. Results of these efforts is the possibility of integrating data from different information systems into our 'CAUSAL EVENT SPACE' concept. Consequently, this concept may generally be appropriate as a database system for analysis of intensive care data. Inclusion of a wide range of questions generated many detailed problems in relation to time causality, time correlation and the

structure of relational databases. In the framework of this project, the next goal will be to refine the algorithms used and to reduce their complexity, in order to provide a profound basis for real time data analysis in intensive care.

In summary we developed a scientific database tool for analysing complex intensive care data. Its structure, power, usability and its potential for future developments make ICDEV a unique instrument working at all levels of intensive care research.

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