A. Michel (1), M. Benson (2), A. Junger (2), G. Sciuk (2), G. Hempelmann (2), J. Dudeck (3), K. Marquardt (1)

Department of Medical and Administrative Data Processing
Department of Anesthesiology and Intensive Care Medicine
(3) Department of Medical Informatics

Justus-Liebig- University, Rudolf-Buchheim-Str. 7, 35392 Giessen, Germany

Abstract. The aim of this project was to develop a cost-effective, standard-based and scalable clinical information system for use in Intensive Care Units (ICUs). The development started in 1998 at the University Giessen, Germany. Since its introduction as the basic documentation system at the ICU ward of the Department of Anesthesiology and Intensive Care Medicine in January 1999, all relevant clinical data of 1723 patients have been recorded. The implementation of the system in two further ICUs is scheduled for the year 2000. The following article describes some of the principal design goals of the system, including the medical vision that drove its interface design, and focuses on the technological underpinnings of the overall system architecture.

## 1. Introduction

Based on a long experience with hospital wide Clinical Information Systems (CIS) and especially the implementation of an Anesthesia Information Management System (AIMS) during the last five years, the decision was made to replace the patient data management system (PDMS) of the operative ICU with a radical new development, focusing on a graphical user interface, standard hardware and software as well as a improved integration into the overall communication architecture of the Giessen university CIS [1,2,3,4]. This resulted in the development of a system called ICUData which has been installed in February 1999 after one year of development.

Many of the basic technological design issues are strongly influenced by the basic assumptions made on the process of critical care medicine. First, the system supports a single patient worksheet for all groups of medical staff, reflecting the high interdependence of treatment between different medical professionals. This worksheet is basically time oriented, since medical data are worthless without the time context that generated them. In a second axis, the worksheet allows parallel presentation of every clinical data item, strongly supporting the contextual interpretation of medical data. This is based on the fact that nearly all data make sense only when interpreted within a clinical context. Furthermore, the system's communication architecture supports shared real time working from multiple workstations on the same patient worksheet, allowing for highly cooperative work within the ICU environment as well as simultaneous data manipulation at the patients bedside and the ward center. Last, the data storage allows for the production of all interesting statistics within a conventional relational database, coupled with all the possibilities of producing online statistics without significant delays from the realtime database. This is critical in a time where data influences the financial management of clinical units.

## 2. Methods

#### The CIS as a collection of client modules

One of the most basic technological design assumptions is the picture of a clinical workstation as a collection of clinical modules from different vendors plugged into a so called software-bus. This is a sharp contrast to the former dinosaurs of monolitical CI-Systems. ICUData fully supports the component-based approach, extending it to the representation of its own functional units. Within this architecture, different functional modules are simply replaceable through other functional equivalent parts, assuming that they adhere to some basic communication rules. Thus, patient selection is accomplished by a module separate from the main workchart application. The same happens with functions such as authorization or different kinds of lab-reporting modules.

## A client centered architecture

ICUData makes extensive use of the graphical capabilities of modern PC-workstations. Because most of the work for data presentation, validation and calculation is done locally within the ICUData-clients, it was possible to fully utilize the workstation's local computing power. Therefore the performance of the clinical interface is primarily a function of workstation performance. Furthermore, this approach removes any limitations which database centric approaches could put on the design of a clinical interface.

## Open standards based messaging as a key to power

The highly modular and client centric approach of ICUData is founded on a message based communications architecture. To open this communication channel to its broadest possible scope, all messaging between ICUData components is based on TCP/IP and the emerging Health-Level-7 (HL7) Standard for medical data transfer [5]. This is accomplished in such a radical way that communication between ICUData components only takes place strictly through HL7. Additionally, to enable the transfer of yet undefined messages, ICUData has placed extensions to the standard conforming to the philosophy of HL7 and will replace its own definitions as soon as widely accepted messages become available. The working group furthermore participates actively within the German HL7-Group.

#### Services based client server approach

The modularity of the client side is also extended to the application servers. ICUData's architecture separates database access from the client side by adding a layer of application servers between theses system components. Application servers reside on the corresponding database machines and receive HL7-messages via TCP-IP from the clients around the network. Every server bundles a functional group of message handlers (services) which consist of logically dependent units (e.g. admin, patient-administration, clinical-results). The servers are heavily multithreaded, enabling the simultaneous processing of multiple messages at a time. The database itself is accessed via dynamically executed SQL-statements. This allows for great flexibility, especially in the field of dynamic query processing for interesting medical data.

#### Realtime data management based on messaging

ICUData introduces a new concept of collective real-time data management by inserting a so called communication master process on the client machines between the client-front-end and the database servers. When the work-chart client is opened for accessing specific patient data, it first connects to its local master communicator to locate the bedside machine of that patient. The master then connects to the bedside master which from then on establishes a continuous data pipeline (based on HL7-messages) in order to instantly report any change in the patient data pool, regardless from which machine it originates. Every data capturing client process (work-chart, medical device interface processes) communicates over this master process which is in turn responsible for the correct forwarding of the generated messages.

#### Medical device interface processes (MDIP)

Currently, medical devices are connected via serial line to the bedside workstations. The communication master dynamically examines the configuration of the devices for a bedside

machine and automatically configures and starts the appropriate MDIP for automatic data capturing. The MDIP primarily acts as a message converter from the proprietary medical device messages into a standard HL7-lab-data message, which is then passed and forwarded via the communication master to interested clients and the appropriate database-application server. Figure 1 demonstrates the overall communication architecture of ICUData.

## Database design

ICUData uses a standard relational database management system (RDBMS), Oracle (Oracle 7, Oracle Corporation), for permanent data storage [6]. Data is logically and physically distributed over several databases (Currently ADT, Admin and Clinical Data), which allows for a parallelization of processing and load balancing. The design of the database parts varies from a stringent relational design in the administrative sections (system administration, patient administration) to a semantic network in the medical data dictionary and a key value timestamp based storage of the clinical data items. The key value timestamp (KVT) approach for storing medical data in conjunction with a medical data dictionary, used for the standardized definition of a clinical vocabulary, has been chosen as a result of own experiences with the HELP-System architecture. Another reason for the KVT approach was a careful examination of the methods chosen in the successful implementations of other large CIS-databases (Regenstrief-CARE, Columbia), which have shown the benefits of such a design for extensive clinical data processing and knowledge drive reasoning [7]. The ICUData project has shown that it is possible to successfully process a vast amount of very heterogeneous clinical data with this highly uniform design and to perform successful and detailed analysis on this data by utilizing only standard database tools.

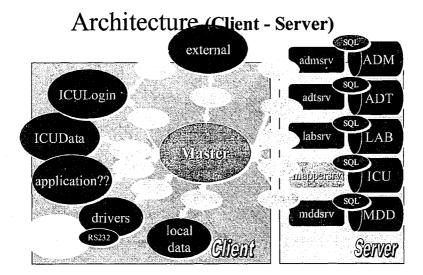


Figure 1: The architecture of the PDMS ICUdata.

#### Hardware requirements

One goal of the ICUData project was to eliminate the need for any specialized and cost intensive computing hardware. It runs on normal PC-clients utilizing WindowsNT-Workstation Software, whereas the database servers currently run on a four processor NT-Cluster machine. All software modules have been written using Microsoft Visual C++ development tools.

# 3. Results

Installation of the hardware and software of the new PDMS took two weeks at the end of 1998. After the system was put into operation on January 26,1999, clinically relevant data of 1723 patients have been documented at 14 beds and at 4 clinical workstations. The average stay in ICU was  $2.84 \pm 9.23$  days.

The interface with the data processing systems of the Departments for Patient Admission, Laboratory, Radiology, Hygiene, Microbiology and Anesthesia have been successfully installed via HL-7 with a communication server. Data exchange with the hospital's pharmacy is planned.

The presentation of all medical parameters in a single window principally won the user's acclaim. Thanks to the programs' functions, training could be performed during clinical routine. The organization of data as single objects in time, similar to the documentation on paper, enables the users to retain their usual interpretation algorithms.

Good performance during simultaneous data manipulation in the patient's worksheet by several users is guaranteed by the communications structure ("master to master communication" bypassing the database) at all times. This structure proved to be practical and advantageous. A user immediately sees data entered at a different client by another user in the patient's worksheet.

The statistic tool contains evaluation options for administrative, economic and quality assurance purposes.

## 4. Outlook

The presented PDMS is an adaptable modular system. Despite the existing basic design architecture, contents may be variable. The systems modular structure of the independent units "communication", "application" and "database" allows a continuous improvement and a variable replacement of single units without total reprogramming of the PDMS. Currently, the object data model is being extended to better reflect complex medical data such as fluid management.

The installation will be extended to the pediatric and neurologic ICUs during the year 2000.

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