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Ways to improve Quality Management at Neonatal Care Units

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Abstract

A Neonatal Care Unit (NICU) is a data-rich environment. An information overload can be observed at point-of-care and hospital enterprise level. Errors may occur just because of the sheer volume of data. The implementation of healthcare information technologies (HIT) can help to enhance the safety, quality and patient-centeredness of care.

Patient data management systems (PDMS) are especially designed software and hardware products for the documentation of patient's condition and treatment at intensive care. These routinely used systems must capture and store the abundance of information generated during the critical care process. Additional, a growing number of quality management systems (QMS) are implemented to provide clinical decision support, computerized physician order entry, rule-based infection monitoring, external quality control, and others. QMS applications and linkages in and among HIT systems can improve patient safety substantial. Communication tasks and asynchronous data exchange between HIT systems are important.

Most HIT systems used at the introduced NICU provide rudimentary data exchange functions, but their data structures are optimized to applications requirements. The data stored at the PDMS database should be used for the QMS application to prevent multiple documentations. Frequent changes of the patient documentation process, subsequent data corrections, and missing essential patient information cause severe problems for data retrieval.

A concept of data export - from actual used PDMS databases – is presented to handle such problems. The solution concept provides calculations, aggregation rules, and export adaptation functionalities. Patient data must be transformed to clearly defined information records for the QMS. The concept evaluation describes success, development process, operating time, customizations, and user satisfaction for implemented projects. It shows the importance of communication mechanisms between PDMS and QMS users. The integration of QMS applications into medical workflow is complex and elaborate methods for data and information exchange are required.

Kurzfassung

In der Intensivmedizin wird eine riesige Menge von Patientendaten verarbeitet, um den Zustand der Patienten zu beurteilen und seine Behandlung zu dokumentieren. Spezielle EDV System werden eingesetzt um die Informationen über den Patienten optimal darzustellen und sein Behandlung zu unterstützen. Patientendaten Management Systeme (PDMS) dienen der bettseitigen Patienten-dokumentation und sind Grundlage für therapeutische Entscheidungen. Zusätzliche Systeme sollen an den Intensivstationen die Qualität der Patientenversorgung verbessern und sichern, wobei die schwer überschaubare Informationsflut dabei aufbereitet werden soll. Solche Systeme sollen möglichst optimal in die Patientenversorgung integriert werden, ohne den Dokumentationsaufwand zu erhöhen.

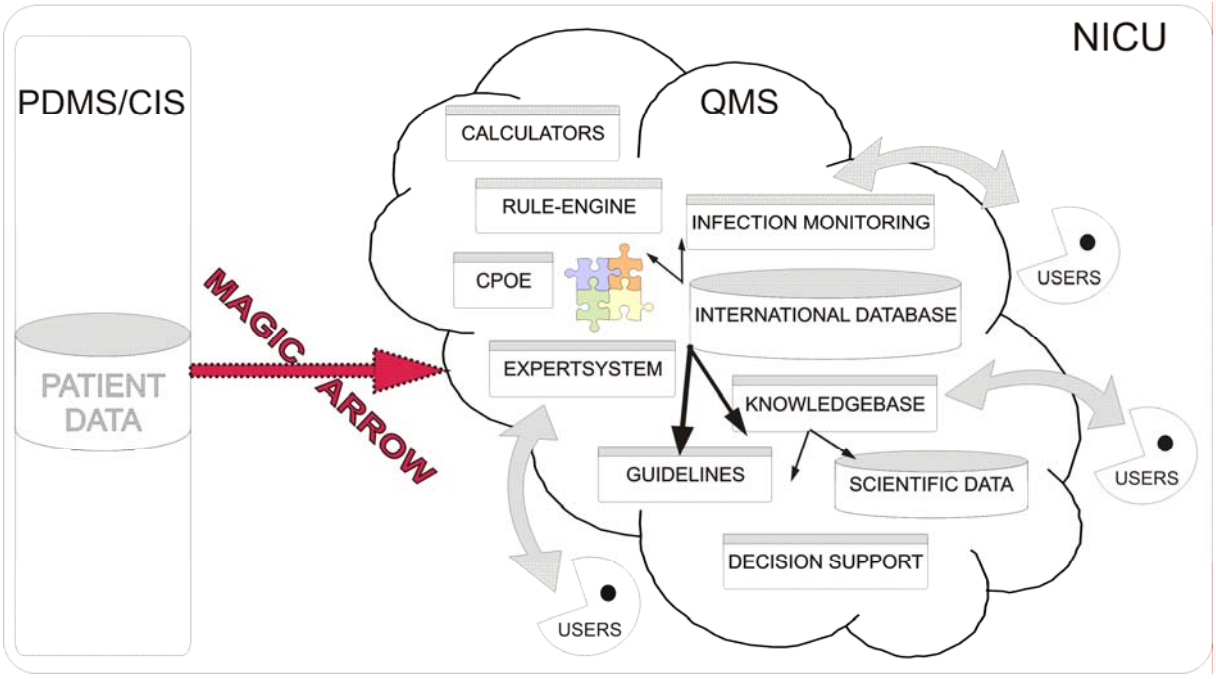
Daher ist ein automatischer Datenaustausch mit dem eingesetzten PDMS notwendig. Die definierten Informationen für solche Anwendungen sollen aus der, an der neonatologischen Intensivstation (NICU) vorhandenen, PDMS Datenbank generiert werden. Die Schwierigkeiten dabei sind, unter anderem, notwendige Änderungen der medizinischen Dokumentation und nachträgliche Korrekturen, beziehungsweise Ergänzungen, von, für die Zusatzsysteme verwendeter, Patientendaten. Die komplexen Abhängigkeiten, die bei der Integration solcher Anwendungen zur Verbesserung der intensivmedizinischen Versorgung entstehen, werden dargestellt und Lösungsmöglichkeiten aufgezeigt.

Ein gut adaptierbares, an mehreren Intensivstationen eingesetztes, Konzept zur Informationsaggregation wird vorgestellt und anhand verwirklichter Projekte evaluiert. Das Einrichten von Kommunikationsschnittstellen zwischen den Applikationen ist dabei unerlässlich um solch zentrale Informationsgewinnung aus der routinemäßigen digitalen Krankengeschichte erfolgreich umzusetzen.

Contents

1 Introduction

How can information for quality management (QM) at an intensive care unit (ICU) be automatically retrieved from standard patient data management systems (PDMS)? Problem areas and some solutions are shown and evaluated at the neonatal intensive care units (NICU) situated at the Vienna General Hospital as part of the Medical University Vienna.



[Figure 01]: Magic arrow from patient data to quality management systems

- **To disenchant the "MAGIC ARROW"**

Most applications developed as quality management systems (QMS) at ICUs, like decisions support systems (DSS), computerized physician order entry (CPOE), rule-based patient monitoring, scientific databases, and others, describe the patient data used for calculation diffuse. At some places in the high sophisticated system descriptions and diagrams there appear a box called patient data which is connected to the system with any arrow. [Figure 01] illustrates such unclear connecting arrow between patient data and additional applications used for QM.
But the description which data and information of patients from which accessible data sources with which restrictions, calculations, formats, data dense, etc. is mostly missing. A characterization of methods and procedures incorporate with the system is found very rarely. The connection between the available patient data and information of an ICU and QMS is essential to allow any well designed and helpful system for daily clinical use. This thesis will describe problems and possible solutions and methods how this "MAGIC ARROW" can work to retrieve the available patient data and information to systems used for quality management exemplary at a real NICU environment.

2 Motivation

My interest in this topic and the motivation to find solutions for the described task derives from my work at the NICU for more than 10 years. I work as a computer specialist to help developing, maintaining, and interchanging with the variety of involved IT systems including some expert systems. The highly needed digital data and information about patients derived from the electronic patient documentation system can be exported with a rather complex data exporting systems. These systems can provide data to several specified IT systems for QM at the NICUs. The methods and systems exporting such specific patient data were developed, improved, and maintained by me over several years.

The important intention at the NICU is using additional IT systems mainly for QM without entering patient data and information twice. The workload at such highly sensitive and technical complex ICUs is very high, so time for documentation has to be kept at a minimum. The NICU is rich of electronically data about patients. An information overload is identifiable at point of care. The multiple IT systems used at the NICUs marginal provide exchange of their data. No standard data interfaces between the used IT systems for QM and the patient documentation system are implemented.

I will describe the problems of data exchange between such systems. My motivation to introduce solutions and a concept to provide the task using documented patient data for systems for QM derives from many concrete projects. Discussions about this problem area and the knowledge about potential solutions are required to improve the integration of multiple useful IT systems for QM at daily medical work. Procedures offered by commercial healthcare IT systems for data exchange must be implemented to the individual needs of an ICU. These tasks need wide experience and knowledge about medical work and documentation as well as programming skills, database design know-how, interfacing cognition and multidisciplinary team working.

The explanations and solutions in this thesis shall bring out how patient data and information can be retrieved for sophisticated IT-systems to improve medical work and patient safety. This important part of data exchange to realize such task is widely underestimate and sometimes ignored by scientific and commercial projects to improve healthcare IT-systems for intensive care.

2.1 Motivation of the NICU

A standardized patient data management system (PDMS) is used at the NICU since 1993. Several additional healthcare IT systems, which should use the data of the PDMS, were added over the years. Therefore, more and better documentation is required without increasing the workload for entering patient data to the systems too much. Most of the additional applications are quality management systems (QMS) to improve quality of care, help to reduce errors, and eventually lower costs of care. The personnel of the NICU, as part of the Medical University of Vienna, teach students and nurses. Scientific research is an important duty beside patients care. Most of the patient data collected at the NICU is needed for medical studies and research on treatment of premature infants with very low

birth weight (vlbw). There is a clear necessity of complete patient - outcome - quality statistics to overlook quality of medical work and to be used as basis for scientific publications.

2.2 Motivation of hospital administration and healthcare organizations

The connectivity of the IT systems at the NICU to the clinical systems, like hospital information system (HIS), shall help to satisfy the need for complied and valid data sets. Hospital's patient record service is used for resource planning and strategic healthcare management. The workload needed for data corrections and for adding missing information shall be kept at a minimum. There are clinical systems connected to, and using data from, the NICU to help reducing errors in treatment and enhance patient safety. Hospital IT systems require many patient data generated at the hospital's units to be exchanged with their systems. Most of that data are needed to strategically reduce costs, or improve quality of care at the hospital.

The exported data from the NICU could be used in an electronic medical record to provide information about the patients to physicians who will treat the patients later. In Austria this record is called ELGA ("Elektronische Gesundheitsakte" More information about the project can be found at [www.arge-elga.at, 2008]). The number of such medical registries increased over the past years. Medical registries can be defined as *"a systematic collection of a clearly defined set of health and demographic data for patients with specific health characteristics, held in a central database for a predefined purpose. <...> Medical registries can serve different purposes—for instance, as a tool to monitor and improve quality of care or as a resource for epidemiological research"* [Arts D.G., et al., 2002 b]. [Arts D.G., et al., 2002 b] presents literature review to define data quality and types and causes of data errors. They introduce a case-study comparing quality of data collected automatically using a PDMS with manually data collection. They concludes "*...in case of automatic data collection, data errors are mostly systematic and caused by programming errors. <...> once detected, this cause can be resolved.* " [Arts D.G., et al., 2002 b].

There exists high interest using information about patients and treatments at ICU, documented with PDMS, to cover increasing reporting and evaluation demands at healthcare. The intentions of different healthcare institutions and organizations to use such patient data vary a lot. Their common goal is to establish systems to manage, and possibly increase, quality of medical care. The closer the benefits of such QMS are to the patients and staff at the NICU the higher is the motivation and the chance to reach the purpose of those systems. It is a demanding job for many involved people of different duties to export data from the standard documentation system to retrieve needed information about the patients for QMS.

3 State of the Art

Health care applications have specific demands and their usage imply challenges for patient care. These applications need special attention, high stability, and must work with minimum technical failures. The implementation of such system must be done carefully, like other high risk information technologies (IT) systems. The medical work flow is influenced by the used applications, like implementation of computer-aided processes at other areas.

The sensitive medical work at intensive care causes implementation of information technologies with already proven techniques. The computer supporting tasks in medicine usually started later than IT implementation at other application areas.

This section will introduce the use of health care IT systems, especially PDMS at intensive care. Systems for quality management are described focused on the data exchange demands to existing PDMS. The difficulty of the system interaction which leads to specified problems is described. Special attention is required on usability of the interaction processes between the connected systems. For improvement of patient treatment quality and outcome with QMS IT applications an efficient data exchange with PDMS is mandatory.

3.1 Information technology (IT) at intensive care

Patient data management systems (PDMS) are especially designed software and hardware products for the documentation of treatment of patients at intensive care units (ICU). These systems can also be called clinical information systems (CIS) in critical care. At modern ICUs the need for additional health care IT applications increases because of the growing complexity and specialization of medical treatment.

3.1.1 Staff cost reduction

A motivation for the use of PDMS was the hope of cost reduction by reducing clinical staff members. The direct benefit to need fewer nurses or physicians because of the use of a PDMS did not work out. As shown in [Saarinen K., Aho M., 2005] the time every nurse spent on direct patient care on an 8 h shift increased by 21 minutes when using a PDMS (increase of 5.5% nursing ($p<0.05$)). The time used for documentation of nursing care increased by 14 minutes of a nurse 8 h shift (increase of 3.7% documentation ($p<0.05$)). In this study CareSuite 6.1 PICIS as CIS was used by the ICUs of a large Finnish central hospital and the possibility of reducing the number of ICU's nurses after the implementation of the PDMS was not observed. The authors did not try to measure any further benefits by using electronic patient information and data from PDMS/CIS beside the replacement of bedside paper documentation.

3.1.2 "To Err is Human"

The most important reason for the development and use of CIS/PDMS at intensive care perhaps are given in the reports of the US Institute of Medicine (IOM) in 1999 and similar inquiries. The public response on this report [Kohn l.T., et al., 2000] surprised many of the health care community. The quality of health care in America committee concluded in the report "To Err is Human" that 98.000 Americans die every year because of preventable medical mistakes they experience during hospitalization. The estimates range from 4% to 20% of all hospitalized patient encountering medical errors and as a result increases charges of $3000 to $9000 per error [IOM Report 20-07-2006].

Many articles discuss the usage of IT systems at healthcare to influence the reduction of such preventable medical errors. In [Bates D.W., et al., 1997] the costs of adverse drug medications are described and in [Raschke R.A., et al., 1998] a compute alert system to prevent injury and medication errors is introduced.

To force implementations and development of healthcare informatics systems was a reaction on the report "To Err is Human". "*Health informatics is the development and assessment of methods and systems for patient data with help of knowledge <…> Health informatics provides tools to control processes in healthcare, acquire medical knowledge and communicate information between people and organizations involved <…> Health informatics is an application-oriented science which must move the technological realization of methods and concepts of information management in medicine forward.*" [Imhoff M., 2000].

3.1.3 Advantages and risks implementing healthcare IT

An ICU is a very data-rich environment. An information overload of the medical staff at point of care can be observed [Martich G.D., et al., 2004]. Physicians and nurses are sometimes confronted with more than 200 variables during a typical morning round. Many data elements need to be turned into information and knowledge. Errors may occur just because of the sheer volume of data. Modern PDMS are not just used to replace bedside paper documentation, but must capture and store the abundance of information generated during the process of critical care.

On the level of hospital enterprise information overload for the complicated reimbursement and account policies lead to an unmatched complexity of data and information.

The implementation of healthcare information technologies (HIT), like PDMS/CIS, computerized physician order entry (CPOE) and decision support systems (DSS) at ICUs can help to enhance the safety, quality and patient-centeredness of care. "*When hospital leaders, clinicians or IT specialists easily assume that HIT will deliver the results promised by vendors, they may overlook likely interplays between new technologies and existing sociotechnical conditions.*" [Harrison M.I., et al., 2007]

Analysis and conceptual models of HITs help to find some unintended consequences of such system interactions. Such unintended consequences produced by HIT implementation at ICU without further system analysis can be:

- More/new work for clinicians: more time for documentation and justification.

- Changes in communication: HIT systems may eliminate informal interactions and redundant checks. HIT systems may create an illusion of communication by believing that entries of orders assure that people see it and act upon it.
- Misrepresenting communication as information transfer: Urgent requests, emergency acts, and workarounds are often not represented in the system. Loss of feedback because the system cannot tell if orders have been carried out before the physician gives the advice.
- Human-Computer interface mostly unsuitable for highly interruptive context.
- Changes in the human power structure of clinical work are possible.
- Overdependence on computers and IT: System failures can create medical errors and potentially impossibility of patient care situation.
- New types of errors at medical treatment may appear.
- And more

[Harrison M.I., et al., 2007]

To spot such consequences of socio technical interactions, managers, designers, clinicians, and researchers need to track HIT-in-use throughout implementation carefully. This kind of tracking requires continuous or repeated evaluation of HIT use and consequences, along with frequent feedback. Successfully installed sophisticated HIT products need a close and long-term work with vendors, consultants, internal designers, clinicians, and IT specialist supporting an iterative refinement process. HIT implementation at ICUs must balance adaption to local needs and practice against maintenance of standardization and system interoperability.

As response to the “To Err is Human” report [Bates D.W., et al., 2001] describes how the frequency and consequences of errors in medical care can be reduced using IT in the provision of care. They describe general and specific recommendations regarding error reduction through the use of HIT. They present the importance of system communication tasks and asynchronous data exchange. In [Bates D.W., et al., 2001] substantial improvement of patient safety especially depends on introduction of clinical decision support systems (DSS) and better linkages in and among HIT systems.

Although HIT can help to reduce error and accident rates, it can cause errors at patient care as well. In [Wentzer H., Bygholm A., 2007] these problems are described as unexpected adverse consequences (UACs) from HIT implementation. All involved users have to be trained using these systems, which can be many persons (depending on hospital size and application area sometimes over thousands) at clinical and administrative level. Continuous support using HIT has to be offered. The success depends highly on the degree of stability, usability, and utility of the system in the specific care domain. So it is important to detect severe usability problems. In order to identify UACs from HIT implementation, it is necessary to draw attention to the spatial and temporal turning points within which communicative relations are framed. These turning points can often be situations and moments of interruption, discontinuity and social-technical tensions in the user communication with the system. Necessary attention focused on health care infrastructure transformation and analyses of human-computer interaction (HCI) of HIT are pointed out well at [Wentzer H., Bygholm A., 2007].

"*To err is not entirely human*": HIT has undoubtedly reduced the risk of serious injury for patients during hospital stays. However, its true potential for preventing medical errors remains only partially realized [Horsky J., et al., 2005].The high demands on HCI and the consequences of user interface design for clinical information systems (CIS) has not be analyzed and described adequate at the time. In [Despont-Gros C., et al., 2005] it is claimed that evaluation of CIS/PDMS, CPOE, and DSS should be connected closely to structured HCI demands on user interactions with the systems. Combining those fields to an integrated model will provide the evaluation process [Despont-Gros C., et al., 2005].

There is currently a need for theoretical frameworks and system design principles grounded in cognitive theory and developed specifically for healthcare environments. Human-centered design of HIT can increase efficiency, usability, ease of learning, user adoption, retention, and satisfaction, and decrease the rate of medical errors [Horsky J., et al., 2005].

[Kaushal R., et al., 2001] describes how HIT improves patient safety in children's health care. Especially, in children's health care HIT interventions, including computerized medication administration records, bar coding, intravenous devices with interfaces, computerized discharge prescriptions and instructions, and other interventions, have great potential for reducing the frequency of errors, because of the need for weight-based drug dosing.

The implementation costs for a PDSM/CIS for some ICUs, operating rooms, and anesthetic recovery rooms of a single hospital can be estimated in the range of 10 – 30 million US$. It is no wonder that hospital administrators often fear to implement such complex technology as PDMS or CIS with no clear-cut vendor provided and a return on investment which is very difficult to be measured. That could be one reason why PDMS/CIS are very rarely implemented at hospitals intensive care, although the need for benchmarking and an electronically documentation of cost relevant diagnoses and treatments is increasing strongly.

The necessity of electronic documentation for cost relevant patient data – and not the improvement of quality of patients care – may be the main argument to implement PDMS/CIS at ICUs.

3.1.4 Quality management with healthcare IT

Accreditation rules for intensive care, like the German Diagnosis Related Rules (DRGs) and the Austrian Center for Documentation & Quality Management in Intensive Care Medicine (ASDI) benchmarking and scoring system, like others, can not be fulfilled without electronic bedside documentation, data capture, and databases with analysis tools. Any benchmark system in intensive care medicine needs data and information from HIT systems used at the ICUs. Such systems should help the units to improve their quality. At present, commercial PDMS/CIS hardly provides standard data export for those benchmarking projects. Special environment with export processes for such datasets must be developed, attended, and serviced by clinical computer specialists.

Such projects cause demand for improvement of integration and acquisition of medical data and information at ICUs. *"Electronic documentation at the bedside becomes extremely productive when the data are used for further analysis and processing (e.g. quality control) and for medical*

process control (e.g. online decision support, electronic protocols) "[Martich G.D., et al., 2004]. Data capture with PDMS/CIS indispensable prerequisite for any workflow automation and any effective implementation of computerized physician order entry (CPOE) and clinical practice guidelines (CPGs) respectively. This advancement of PDMS/CIS will allow the broadest control over and management of the process of care with computerized protocols, clinical pathways, and CPGs.

At the moment there are just very few possibilities to integrate those methods in standard commercial PDMS. But it is one of the most focused future trends of PDMS and CIS development for intensive care. Rudimentary functions for CPOE and DSS integration are offered by most systems but are not routinely used and integrated into the medical treatment process at the time. *"Physician order entry can be considered the key to medical process control. It is probably the most complex functionality in any CIS."* [Martich G.D., et al., 2004]

It is important for complex medical information systems to fit well into the clinician's workflow otherwise medical users will activate those functionalities seldom. It is also possible that some changes in the way health care professionals think and act are required to let them start to use such functions at medical practice.

Most decision support applications and any kind of qualified data analysis require consistent and standardized medical vocabularies, which are still lacking in all developed countries despite the formidable effort of international and national organizations. For all the advantages of PDMS of continuous high quality documentation and comparability of data due to the availability of a database there is still a lack of standards for the subsequent exchange of data [Heinrichs W., 1998].

Quality control in the presence of careful planning can become the important advantage of health care IT systems.

3.1.5 Requirements of healthcare IT

IT systems used at intensive care must achieve specific juridical and technical requirements. The standards for those systems are high because they process sensitive patient data and system failures can possibly cause life-threatening consequences.

- Data security:
  The demand that it should be known which individuals have entered, corrected or even had accessed patient specific data can hardly be fulfilled with traditional paper documentation. The protection of high sensitive private patient data must be observed and is defined in laws of most countries. The actual data protection act in Austria e.g. is published as [DSG 2000]. To be in compliance with the law it is necessary to use HIT Systems with the functionality of a personalized electronic time-date-stamp protocol and clear user access concepts. Traditional paper documentation at ICUs can hardly achieve the laws.

- Availability of medical records:
  Beside the functionality of permanent displaying patient data and information at point of care and wherever needed at the unit and storing these data and information for the use of quality

managements systems, there is a juridical obligation to store these information and data in special medical archives as not editable documents for the use of any inquisition of medical decision and medical errors. As verifications for such inquisitions it is necessary to examine at which time a medical user entered, corrected or had access to the information and data about patient condition and treatment. There are different strategies used by the HIT systems to fulfill this specification. Only ICUs using electronic documentation at point of care can potentially comply with the juridical requirements.

PDMS/CIS are health care IT systems used at intensive care. Because of these special standards and the imperative to be very stable and failsafe, commercial PDMS/CIS production must achieve the demands defined by specific laws about medical product safety. Before these PDMS/CIS products can be sold they have to prove that all requirements for these products postulated in that specific law are fulfilled.

A number of commercial PDMS/CIS and some specific developed systems are described and evaluated in [de Keizer N.F., et al., 1998].

The [Table 01] shows an actual list of some commercial PDMS/CIS products and vendors.

PRODUCT	COMPANY	INFORMATION AT:
MetaVision (MV)	iMDsoft	http://www.imd-soft.com
ICIP	PHILIPS	http://www.medical.philips.com
Centricity	GE Healthcare	http://www.gehealthcare.com
Intensive Care Manager (ICM)	Dräger Medical, Siemens	http://www.draeger.com
ChartAssist	Dräger Medical, Siemens	http://www.draeger.com
QCare Suite	Critical Care Company (C3)	http://www.c3.be
COPRA	COPRA	http://www.copra-system.de
ICUData	IMESCO	http://www.imeso.de
PICIS	PICIS	http://www.picis.com

[Table 01]: List of some commercial PDMS

3.1.6 Conflicting demands of PDMS documentation

Many of the highly needed requests PDMS users at ICUs ask for are diverging. Conflicting demands on beside PDMS documentation are specified by nurses and physicians of the units. PDMS implementation at an ICU must find a well balanced compromise between these differing requirements. Some needs must be put aside in favor of others. A priority order for all demands has to be found to decide which functions shall be implemented.

- Fast and time relevant data entry ←→ High quality, integrity and completeness of data
  Mandatory fields can help a lot to force users entering highly needed information of a patient, but slow down the documentation process during the procedure of very time relevant patient admission tasks. An emergency admission should be possible with a minimum of data entries needed. But otherwise some parameters which are highly needed for further processing will be

left empty for some time. The configuration of mandatory fields must be done very carefully and a process to remind users to enter missing or incomplete data should be implemented.

- High security of patient data access ←→ Fast and time relevant data entry
  If time counts and the access to patient data and information must to be fast and direct, there is no time for entering any passwords or user identifications. When the PDMS is used at point of care the user access must be fast and easy because nobody without proper rights to see the patient information shall be at patient bed. Access to PDMS with user identification and password is strictly necessary for all non bedside usage and for quality management tools. Other solutions for user identification like fingerprint scanning, card identification, picture recognition and some more were tested and validated but could not reach the demands for medical practice. The special dimension of Human Computer Interaction (HCI) for clinical information systems (CIS) is evaluated in [Despont-Gros C., et al., 2005].

- High quality, integrity and completeness of data ←→ High flexibility of documentation for patient information, treatments and diagnoses
  The use of patient data for any further processing and the integration of quality management tools needs highly structured and well defined range of data. During medical and nursing practice the documentation should be fast, flexible and easy to read with common phrases and values for the users. Sometimes the wish of PDMS users for entering patient information as free text into a clipboard is formulated. This kind of patient documentation data is very complex to extract information for other medical IT-systems for QM. On the other hand a step by step entering of patient data is unacceptable for medical users. So a balanced compromise of the demands of data reuse and fast and easy data entering must be found. PDMS/CIS configuration must reflect the data input specifications. Special tools and functions for data interpretation at export should be developed. Such methods will be described later.

- Flexibility of documentation ←→ System stability
  Stable and fixed data structure concepts with few interfaces and specified unchangeable data processing will make the system more failsafe, easier maintainable and stable. But the adaptation of the system to cover the changes in medical treatment and documentation needs will become very complex and expensive, sometimes nearly impossible. The demand of high flexible and stable structures is a real challenge at implementation of PDMS/CIS.

- Easy, fast and recognizable visualization of patient data ←→ Completeness of data with high resolutions
  To consider the use of all accessible patient data at any time as desirable it should be aware that the visualization possibilities and storage capacity can reach a limit. The fast and clear recognition of important information about the patient condition is only possible with a limited number of parameters at the same time. Special visualization concepts, like metaphor graphics, can help to solve the problem of too many parameters about patient condition at ICUs [Horn W., et al., 2001]. The reduction of data resolution or number of parameters may be reasonable because it has been shown in [Martich G.D., et al., 2004] that fast response times are what

medical users value most in their IT systems. The importance of good system performance should always stay in mind when implementing and configure PDMS/CIS.

These and other problems caused by diverging medical user demands especially at intensive care should be conscious when integrating systems for QM. The retrieval of patient information collected at point of care is a challenging task with the necessity to consider many aspects and knowledge about the manner the data are entered and how they can be interpreted.

3.2 Quality management systems (QMS) at intensive care

At prior section the need to improve HIT systems by integrating systems for quality management was mentioned. Those systems are defined, classified, and described at this section. A possibility to use data from PDMS and other HIT is a basic claim for those QMS.

3.2.1 Definition of QMS

Wikipedia shows following definition for QMS: "*Quality Management System (QMS) can be defined as a set of policies, processes and procedures required for planning and execution (production / development / service) in the core business area of an organization.*" International Organization for Standardization (ISO) offers a complete and detailed definition and additional some documents about Quality Management Principles. [http://www.iso.org]

In [Marley K.A., et al., 2004] quality from medical view is defined: In healthcare organizations the definition for quality can be divided into its two key dimensions - clinical quality and process quality. Clinical quality is the technical quality delivered and results from medical procedures. In contrast, process quality is the result of the service delivery process engaged during and outside of the medical procedures. Clinical quality is determined by medical outcomes while process quality results from patients' perception of "how" the service was created and delivered.

There is a wide range of definitions using terms like "Health Risk Management", "Patient Safety", "Health and Safety Management" and others. In the context of "quality of care" many specific definitions and definitions from organizations exists.

In this thesis the term Quality Management Systems (QMS) is used for any computer aided method used to improve quality of patient treatment and outcome, not limited to survival but also related to quality of life, and helps to decrease medical errors. For example, this can be done by systems to validate research hypothesis, optimising patient nutrition, or monitor infections at ICUs.

There is a wide vary of systems used to improve and control quality at intensive care units. Many of them have different goals and concepts to achieve quality improvement.

Quality assessment at ICUs has general concepts for structure, process, and result of medical treatment. Some common goals of QMS by measuring specific performance parameters at an ICU are: outcome-statistics, medication safety, resource planning, infection control and others.

3.2.2 Selection and development of QMS

It is a very complex and challenging task to define and validate QMS for ICUs. Some systems were developed by the Austrian Center for Documentation & Quality Management in Intensive Care Medicine (ASDI) and the Vermont Oxford Network for external and internal evaluation of quality. Another example for QMS is the Dutch National Intensive Care Evaluation (NICE) registry set up in 1996. This system is described in [Arts D.G., et al., 2002 a]. These and some other systems used for quality management at neonatal care units (NICU) are described at the solutions and evaluation sections.

QMS used at intensive care can be classified by their use for internal and external quality control. Examples for external quality management systems are the benchmarking projects with the ASDI data set of the Austrian Center for Documentation & Quality Management in Intensive Care Medicine (ASDI) and the Vermont Oxford Network data definitions for newborn infants with a birth weight lower than 1500 g (vlbw). More information about ASDI can be found at [www.asdi.ac.at, 2008] and about the Vermont Oxford Network at [www.vtoxford.org, 2008].

Internal quality control, for example, can be done by generating statistical annual reports out of well defined patient parameters. Treatment statistics correlated to patient diagnoses and intervention measurement can be used for such internal QM. For monitoring intensive care unit performance, beside the use of statistical charts, special designed scores, like APACHE II, SAPS II, SNAP and others are widely used. A list of common critical care scoring systems is shown in [Table 02].

NAME		USE	PATIENTS	ITEMS	TIME
APACHE II	Acute Physiology and Chronic Health Evaluation System	physiology	adult ICU-patients	12	first 24 h, daily
SAPS II	Simplified Acute Physiology Score: using GCS	physiology, predictive	adult ICU-patients	15	first 24 h, daily
SOFA	Sequential Organ Failure Assessment: using GCS	physiology	Organ dysfunctions	8	any time
TRISS	TRauma Injury Severity Score: combine Revised Trauma Scores (RTS), GCS and Injury Severity Scores (ISS)	predictive	Trauma patients	13	admission
SNAP	Score for Neonatal Acute Physiology	physiology, predictive	Newborn babies	30	first 24 h
CRIB	Clinical Risk Index for Babies	predictive	Neonates VLBW	6	first 12 h
PRISM III	Pediatric Risk of Mortality	physiology, predictive	Children	24	first 24 h

TISS 28	Simplified Therapeutic Intervention Scoring System	interventions	Adults	28	daily
NTISS	Neonatal Therapeutical Intervention Score System	interventions	Infants	48	daily
PTISS	Pediatric Therapeutical Intervention Score System	interventions	Children	59	daily
GCS	Glascow Coma Scale/Score	neurology	with adaption for any patients	3	any time
AIS	Abbreviated Injury Scale	anatomical	injury of single body region	1	any time
ISS	Injury Severity Score: 6 body region AIS	anatomical	multiple injuries	6	any time
ASA	American Society of Anaesthesiologists	surgery	Risk assessment for surgery	1	before surgery

[Table 02]: List of some common Scores at intensive care

The problem of developing systems for quality management can be shown by the example of an easy outcome statistic. The quality of medical treatment can not be shown by such statistic without a predictive analyze. The outcome of an ICU can rise but the quality of treatment drop if the predicted unit outcome is higher than the achieved.

Many of the parameters needed for such prediction are very sensitive and must be measured exactly as defined. The statistical evaluation for such systems and scores defines a small interpretable range for each parameter. The use of external quality control by comparing values of a specific ICU with the sum of all other ICUs can also only be successful if every parameter is well described and measured exactly the same way at each unit. If an ICU has a great vary of different types of reasons for patient admission, it will be more complex to find comparable parameters to measure the quality of treatment. A NICU is a rather easy unit to control the quality because of its similar reasons for patient care. Most of the admitted patients are premature infants with a birth weight of less than 2000 gm.

Most QMS like infection control, systems using specific diagnoses, like German DRGs, intervention measuring and others have a restrict definition of the required parameters as well.

3.2.3 QMS using PDMS data

The commendable high motivation using systems for quality improvement at ICUs, QMS shall not cause multiple documentations of similar patient data and medical treatment information. The workload at ICUs is rather high and any additional documentation should be avoided. Therefore, it is very important to get any possible information needed by the QMS from the data of the used PDMS with a minimum of adaptation of the standard patient documentation process.

In summary it can be mentioned that the integration of quality management IT-System using an existing PDMS/CIS at an ICU requires a novel, interdisciplinary team approach.

3.2.3.1 Differences of QMS and PDMS data

Data collected for documentation at point of care with a PDMS may have a completely different meaning than the data needed for a specific QMS.

As mentioned before most systems for quality management have their own specific and strictly defined dataset. It is very important to reuse the data from the PDMS for such QM-systems to know on which terms and conditions the values and information about patients and treatment were entered. To decide if a specific parameter can be used from the PDMS all restrictions defined must be achieved. It must be clear who – when – why – and under which circumstances the parameter values were documented. It might be necessary to calculate needed information for the QMS from different PDSM parameters. A wide knowledge about the use of the PDMS at point of care by physicians and nurses is essential just as a complete knowledge about all integrated devices which send data to the PDMS interfaces.

Although some parameters needed for QMS seems to be similar and look like the parameter documented with the PDMS, they can not be used for the QMS without checking out and verifying if they meet all restrictions and documentation rules defined for the dataset of the QMS. If some specific items, like a defined diagnosis of the patient can not be found directly in the PDMS Data, the needed information can sometimes be documented in a more complex or hidden way at the patient record. If an item values is not found in the documentation of the patient it does not mean by sure that the patient does not indicate the specific item. It is different if some problem or symptom, like fever, is not found in the patient documentation and the documented information about the not existent symptom. It is a common mistake to interpret a missing symptom like a documented negation.

3.2.3.2 Quality of PDMS data used for QMS

Quality of data and information of a PDMS also depends on the methods and procedures used to extract and export them. A well structured concept and some technical methods to integrate knowledge about the documentation and needed parameters are necessary for information retrieval from PDMS for the use by QMSs.

> Definition of data quality from [Arts D.G., et al., 2002 b]:
> According to the International Standards Organisation (ISO) definition, ‘quality’ is “the totality of features and characteristics of an entity that bears on its ability to satisfy stated and implied needs”. (ISO 8402-1986, Quality-Vocabulary) Similarly, in the context of a medical registry, ‘data quality’ can be defined as “the totality of features and characteristics of a data set that bear on its ability to satisfy the needs that result from the intended use of the data”.

If the retrieval of specific patient information from the existing documentation systems seems too complex and the data are not needed permanent but just for defined time period the idea of manually collection of the data will appear. Beside the required additional work the extra collected

information can not be reused for other systems without a concept of concerted data and information of patient for the unit. It should be aware that the data quality of manually particular entered patient information for specific studies can be worse than reuse of patient documentations data from a PDMS. Compared to other commonly used data sources to obtain information for clinical research the data from a commercial PDSM/CIS without any correction methods or other additive procedures for data validation is an acceptable source of ICU patient data [Ward N.S., et al., 2004].

To achieve good quality of data for QMSs some common methods can not be used. The definition of only very few mandatory fields for documentation at point of care is possible because of the priority for accurate patient care. These restrictions and other requirements for PDMS like the primal need of displaying information are specified later at the PDMS description section.

Good data quality can be obtained from automatically imported values from external devices, like vital monitoring, laboratory values, ventilation machines. There are several methods to improve the quality of patient documentation. It was shown that the implementation of information technologies reduces medical errors. Using bar-coding medication at point-of-care information systems reduce medication error rate by 60% to 80% [Anderson J.G., et al., 2003].

Special methods and procedures should be integrated to the information retrieval concept to get valuable data quality for QMS.

There are many possibilities to store medical Information about the patient in different data fields and sometimes rather similar information is documented at different sections and forms of the PDMS. So it could be possible, and sometimes necessary, to use the combination of different data fields to get specific information of a patient. For example, the application of catecholamine to a patient in a specified time interval can be documented in the medication section as well as the intake – outtake section with a specified volume. Only the combination of this information can calculate a requested severity code of the patient vital condition.

On the other hand, single specific information can be documented in different kinds and areas of the PDSM. For example, the body temperature of a patient can be measured and documented in different ways. The temperature values are not directly comparably and can only be combined with further calculation because an axillary measured value is about 1.4 ° C lower than a value measured from core blood.

3.2.4 Classification of QMS data access by time relevance

QMS at intensive care need to access clear defined datasets which should be exported from the used PDMS/CIS. The problems rising with the necessity for such datasets for QMS are shown in the next sections. The process to get the needed information and data can be classified by time relevance:

- Ad hoc data → event triggered
  The export of the data for a specific patient or time period is executed on demand. A user interface to select a patient and/or time period and start the data fetch is needed. This way of PDMS data access is used mainly for research projects and the analyze of special question on patient treatment.

- Statistical data → periodical
  The repeated need of statistical charts and measurements lead to a periodical export of necessary data and information. This can be done by scheduled procedures or on demand. The need of some user interface exists mostly for selection of time borders or other definitions on the required statistic.

- Permanent data → time triggered
  External QMS need defined datasets exported from the PDMS/CIS frequently. IT system used to validate and check such patient datasets, for internal used QMS as well, will need a permanent data access as near as possible to actual patient data. This is required because validations and corrections of data should be done during actual patient care. This time triggered data access for QMS can be done using a special designed data mart. The concept and solutions for integrating QMS into an existing NICU environment described later, mainly implement such permanent, time triggered data export via data marts.

Some QMSs do not access PDMS/CIS patient data. Such systems use data from other interfaces or do not have any data import functions. All patient information for those systems must be entered manually. There can be QMS with direct access to the documented data of the PDMS without any explicit import/export functions. These systems can be classified as special type accessing patient information with no explicit data export process necessary. Those systems handle data corrections and calculation executions with implemented specific functions.

Data mapping methods and other functions to get the correct data for needed information are essential for all export classes. This is particular required for direct data access.

3.2.5 Other data sources for QMS

QMS may need data from other HIT systems used at the ICU as well. The data transfer using interfaces (e.g. HL7) of data source systems like, patient monitoring, special lab environment, ventilation machines and others have the demand of hardware and software to store the data. A separate patient identification system to link the data from different sources to the correct patients is required. In most cases it will be easier using PDMS/CIS as data source for QMS because data storage, backup and a common patient identification for data from the external sources already exists. Integration of that external data sources to the PDMS with interfaces is obviously required.

Health Level 7 (HL7) is ANSI-accredited information exchange protocol standards for electronically defining clinical and administrative data in the healthcare industry. HL7 is one of several standards developing organizations in healthcare. The "7" comes from application layer 7 in the OSI .More information can be found at [www.hl7.org, 2008].

3.3 Specific problems: PDMS used for QMS

- Correction – Problem: Data from PDMS can be corrected by users, after the QMS already accessed them and generated output with the wrong data.

- Time – Problem: Data for QMS are needed at specific time to generate output, but can then be missing at the PDMS and entered later.

A problem using data from PDMS for QMS is the time when information is entered and possibly corrected by nurses, physician and other users. Some important information, needed for further calculation, or triggering a connected QMS, may be documented some time after the calculation of the system shall start. If data of the patient documentation is corrected after a connected QMS already calculated a needed value a recalculation must start and replace the result. This can lead to the necessity of complex communication procedures between the systems. Most PDMS have a strictly implemented time limit till then data in time-oriented spreadsheets can be entered or corrected. This limit helps to find safe states for validity of the QMS. A common time range data can be entered or corrected is 24 hours. The disadvantage of this standard is the impossibility entering or correcting data after that time limit. Some wrong or missing information may remain unchanged at PDMS documentation. Only additional information entered later can point to the wrong or missing values. Nevertheless that process matches clinical patient documentation practice best, because it is clearly shown at what time which information was provided by the system for the patient. There are some other reasons generating wrong or missing data in a medical documentation system like configuration or interface misuse or data communication errors.

"*Because many electronic records"* (e.g. from QMS) "*and ordering systems integrate active decision-support functions that are triggered either by user actions or changes in stored data, the understanding of medical decision-making and reasoning processes is a prerequisite for assuring that such systems present the right information, in the most appropriate form, at exactly the time when it is needed*." [Horsky J., et al., 2005].

This complex problem of data and information integrity and completeness of medical documentation will be discussed in more detail at later sections. Methods to deal with this problem for specific QMS will be introduced at the solution section.

- Density – Problem: Data are not documented at the PDMS/CIS at required time frequency for QMS.

Data about patients may not be documented often enough at the PDMS to be used as source of specific QMSs. Systems for quality management may require vital parameter of a patient every minute or less. If the PDMS stores data with some statistic calculation at a lower time interval like every 15 minutes the data can not be used correctly. It may be necessary to use additional data sources, like vital monitoring interfaces, for such systems. The integration of QMS at intensive care units needs a mature concept to fulfill all demands of such Systems.

- Structure – Problem: Data required for QMS are stored in a complex and nested PDMS database structure.

The time-oriented documentation of events and medical or nursing actions together with continuous data cause a complex structure of information representation at PDMS. This generates a very complex and nested database structure in most cases. The complexity of database structure is also caused by the demands of high flexibility and customizability of medical patient documentation.

HIT systems for patient documentation can be adapted to the users needs. The configured operations of patient documentation at intensive care often change several times a year. Reasons for those adoptions can be new external data sources accessed from interfaces, new medication rules and updated drug lists. Other necessities to customize the documentation process exist as well. These changing procedures create not only complexity of databases structure at patient documentation HIT but determine that more than 80% of the data in such databases are information about the documentation as well. So PDMS databases may contain a huge amount of metadata information (information about the patient data) and rather spares real patient data values.

- Patient admission identification – Problem: Data of a specific patient admission can sometimes not be identified easily in the PDMS/CIS.

Correct patient identification can be difficult using PDMS data as source for QMS. The name of patient can change very likely at neonatal intensive care units (NICU). Sometimes even data of birth values especially at multiple births do no help identifying patients. For QMS it is essential to connect data records of patient correctly. Work flow at intensive care put documentation task behind patient treatment. Emergency admissions without any patient identification are routine at ICUs. Any HIT used at intensive care must handle that problem and should provide functions to connect measured or entered values to the patients retrospectively.

3.4 General problems of PDMS data export

Like at any other time relevant data export there are general problems using PDMS databases as source for QMS. The demand of very stable and failsafe DB systems with high reliability to provide permanent data access source to export data to QMS which are integrative used in the process of patient care. High performance database systems for continuous reading and writing processes are necessary to assure the needed essential information for the QMS can be retrieved within given time limits. That could be a great amount of data required to be exported from the database of the PDMS to calculate and process information for the connected QMS. The database volume of a PDMS can be very high if a long time period of patient documentation data, like some years are stored and can be accessed for any export.

Database requirements for storage organization, backup functions, data security and others can only be achieved by a commercial professional database system. Especially the demand of a complex security concept, to ensure that data can only be read and written by users and systems

with proper privileges, can result in complicate procedures for system communication. Different privilege for several ICUs with PDMS, specific patient types and kind of patient data may be demanded. These general database export problems must be handled and solved together with the specific medical documentation problems to develop a satisfying solution of QMS integrating at ICUs.

3.5 Expectations for successful QMS integration

HIT like PDMS implemented at intensive care can improve patient safety. Also there are admonitions of unexpected adverse consequences (UACs) which can occur from HIT implementation at intensive care. At the time the number of ICUs equipped with PDMS/CIS raises rapidly in Europe and most developed countries.

High sophisticated applications developed for quality improvement at intensive care result from multidisciplinary research projects. The number of scientific papers about computerized physician order entry (CPOE), clinical practice guidelines (CPG), decision support systems (DSS) and knowledge based medical supporting systems is enormous. Most of the described systems should use computerized patient data from PDMS or other possible sources. Although there are warnings about UACs possibly caused by system interactions between PDMS and additional QMS applications, such necessary data exchange procedures should certainly be developed and implemented.

The number of medical registries used for external quality control increased over the past years as well. Such systems use defined patient data records which should automatically be exported from PDMS/CIS.

Bedside PDMS documentation was identified as extremely productive when the data are used for further analysis and processing with QMS. This advancement of PDMS/CIS allows CPGs and computerized protocols integration to manage the process of care.

In contrast to that illustrated cognitions there could be rarely found any publications about successful integration of PDMS usage with such QMS applications at concrete medical practice. At real hospital IT setups exists rather no concepts for such system integrations. Every implementation of a new HIT system generates individual data exchange processes with more or less successful functionality and user satisfaction.

There exists the exigency of generally applicable concepts for integration of QMS at existing PDMS environment at intensive care. Commercial PDMS/CIS applications provide any kind of patient data export or other possibilities to access that information. Most applications developed for quality improvement at ICU, including medical registers and benchmarking projects, provide patient data import functionality. The task to connect PDMS/CIS with such systems is marginal documented and displayed very seldom. Some modern PDMS/CIS support functions to integrate such special applications into the bedside documentation system. But these functions are nearly never used because of the complex integration process and the diverging demands on patient data and information for such QMS.

Which generally applicable concept for QMS integration with existing PDMS environment can be implemented successfully at ICUs? Which recommendations exist for such HIT applications? How can such patient data retrieval mechanism be maintained and kept accurate for changing patient documentation procedures? What must be considered to deal with subsequent data corrections and missing essential patient information? How can calculations and aggregation rules for required patient parameters be implemented at data export processes? Which future demands and developments for such systems can be expected?

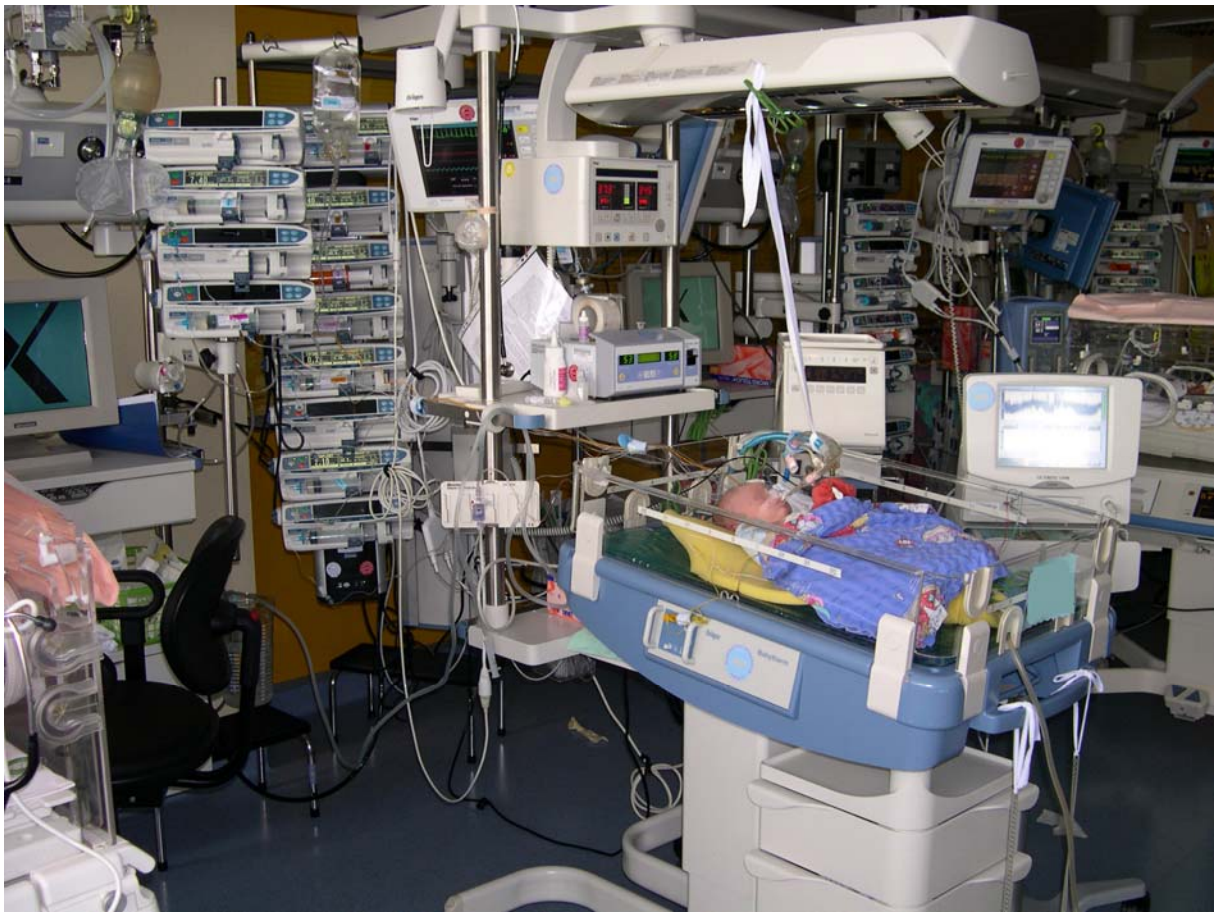
The following sections introduce concrete intensive care units for neonates with long term used PDMS environment. Several QMS applications are presented subsequent. This thesis will picture out a concept for specific solutions connecting QMS to existing PDMS environment to reuse data from patient documentation. To evaluate those solutions the success and failure of realized projects using that concept are described at the evaluation section. The explanations are the attempt to answer some of the above-mentioned questions.

The illustrations of the QMS integration at existing and used intensive care environment shall show system integration problems and some solutions to help developers and researchers of such HIT systems by establishing understanding about complexity of patient data requisition. The focus of the presented solutions points on frequently changing documentation process and systems handling with input corrections and missing values. The knowledge about real intensive care working processes shall help to prevent development of ineffective data exchange mechanism for applications for quality improvement.

Another important issue about HIT at intensive care using applications for QMS is related to analysis and development of Human-Computer Interaction (HCI). But that important subject is not further carried out at this thesis.

4 NICU at AKH

The NICU is located at the Vienna General Hospital (AKH) in Austria. This hospital with more than 550.000 ambulant patient visits and nearly 100.000 patient admissions has 21 Intensive Care Units, 78 nursing wards and more than 70 rooms for Surgery. Approximately 1500 physicians are working there with an overall number of more than 9.000 employees. More information can be found at [www.akhwien.at, 2088]. This university hospital is the part of the Medical University of Vienna with was founded in 2004. Research and teaching is done there at 31 university clinics and clinical institutes and 12 medical-theoretical departments. About 5.000 scientific employees and 8.500 students do research in different specific fields like intensive care and computer science. More information can be found at [www.meduniwien.ac.at, 2008]. Scientific work and work on patient care is well embedded in a large amount of colleges with interests at research and improving of patient care at this hospital.



[Figure 02]: NICU at the Vienna General Hospital (AKH) of the Medical University of Vienna

When the department of Pediatrics of the University Hospital Vienna was opened at the new building one large neonatal care unit (NICU) with 18 beds exists In 1996 a second NICU with 8 beds was established next to the delivery room of the perinatal center. Some years later this NICU has been

extended to 12 beds. In 2006 an additional neonatal intermediate care unit opened at the department of pediatrics and adolescent medicine. At the present there are two NICUs with 12 beds and an intermediate neonatal care unit with also 12 beds. All three wards have nearly the same technical equipment.
A typical patient history starts with the admission of the premature infant at the NICU next to the delivery room. After some time like days, when the patient is well enough for transportation, the baby is transferred to the NICU at the department of pediatrics located nearby. If the high intensity of care is not necessary any more but the small patient is not well enough to be discharged, the infant will be transferred to the neonatal intermediate care unit. Discharges of any reasons are possible from all three Units. Sometimes a transfer back to the NICU can be necessary.

More than 500 newborn infants, mostly premature infants with a birth weight of less than 2000 g are admitted at the three NICUs every year. Causes of admission are:

- Problems of immaturity, mainly of the lungs and the gastrointestinal tract causing breathing and feeding problems. 150 to 200 newborn infants are very low birth weight (vlbw) infants with a birth weight of less than 1500 g, and 100 of them are extreme low birth weight (elbw) infants with a birth weight of less than 1000g. Usually the smaller the birth weight, the larger the problems and the more severe the complications, like generalized infection (septicaemia) and cardiovascular problems. Both may lead to impaired brain perfusion causing even permanent brain damage due to hypoxemia, intracerebral hemorrhage, and ventricular enlargement (hydrocephalus).
- Problems of perinatal infections, either prenatal or hospital acquired generalized infections that may cause organ dysfunction, cardiovascular problems, and brain damage.
- Other problems, like genetic disorders, malformations, surgical problems etc.

Diagnosis of problems in the NICU environment mostly require clinical skills and experience, a specialized lab that may process very little blood samples, and bed side ultrasound technology for uncovering organ specific (brain, cardiovascular, renal, liver etc.) structural and perfusion problems.

Treatment usually last for prolonged periods of time (in elbw infants for months) at varying levels of intensity. Options usually cover providing a neutral thermal environment in the incubator or heat bed, delivery of oxygen and or mechanical ventilation, carefully planned parenteral and/or enteral nutrition, and various drugs that may be delivered as continuous or discontinuous infusions or by other routes, e.g. artificial surfactant via the trachea. Treatment should always consider that the premature newborn infant is very fragile, has immature organs and an immature immune system, is still maturing, and reacts very sensitively to stress. The best clinical results are usually achieved in units that provide the least invasive diagnosis and treatment.

[Figure 03]: NICU at the Vienna General Hospital of the Medical University of Vienna

Computer systems facilitating clinical information and administration have been developed especially for the intensive care environment in the late seventies and early eighties is depict at [Fretschner R.,et al., 2001]. With the advent of commercially available patient data management systems (PDMS), information technology has also become interesting for the NICU environment. PDMS provides very structured overviews and mappings of a patient's condition, a specific advantage in a clinical environment that needs good overview for rapid decisions.

Although the expectations in the abilities of artificial intelligence systems formulated in the 70s have not held true, there are knowledge-based information, decision support, and data visualization systems that have been successfully implemented in the NICU environment. One example is VIE-PNN described at [Horn W., et al., 2002 a], a system that facilitates calculations of parenteral and enteral nutrition for newborn infants. Another domain of computer applications in the NICU environment are systems that help in compiling and analyzing data for quality control. Those systems are described detailed at the QMS at NICU section.

5 PDMS of the NICU

Computers with patient data management systems (PDMS) were clinically used at intensive care units since the 1970s. They start to replace handwritten chartings and medical files at patient's beds but till this day many wards for intensive care, even in Europe and USA, do not use computer supported documentation. Only a very small minority of ICUs are using paperless documentation. The automation of health care with use of computerized information systems has not been as widely accepted and implemented as computer technology use in all other sectors [Martich G.D., et al., 2004]. Some of the possible reasons, like the need of consistent and standardized medical vocabularies, the need of fast response times and how important it is that such IT-Systems fit into clinician's workflow will be discussed later.

At time when the new "AKH-Vienna" was build and equipped with technical environment it was decided to install a PDMS at all ICUs, operation rooms (OR), and anesthetic recovery rooms. So the NICU gets the chance to start computerized documentation as well. The PDMS CareVue by Hewlett Packard was originally designed for adult's intensive care. But like most other ICUs at the hospital it was necessary to adapted and configure the system for the specific needs. It possibly was an easier task to lunch such a system together with the opening of a new build hospital. The implementation of a PDMS is extremely challenging and time-consuming task [Fretschner R., et al., 2001].

After increasing need for data export, especially to quality management systems (QMS), a project called "common configuration" started for the PDMS in 2000 and was implemented 2003. The many individual configurations for every unit's specific needs had to fit in a single common documentation. This huge requirement needed more than two years to be fulfilled. It was essential display patient data completely from other ICUs or the OR and anesthetic recovery rooms at actual point of care. This standardizing of medical documentation was important for patient information retrieval needed for the additional QMS which will be described at later sections. The individual configuration of the NICU PDMS was not replaced during that project because of the great differences in medical treatment and parameter ranges. At the NICU exits many specific items exclusively needed at that unit type like birth weight, gestational age (GA), APGAR-Score, and many more.

The configuration of the NICU PDMS established in 1993 is used, with some changes in 2000 for specific quality control parameters and other minor adjustments, until now. Most configuration changes were caused by integrating new external data sources like ventilators, patient monitoring and other systems. All three PDMS of the two NICUs and the neonatal intermediate care unit have the same configuration. The main reason is the required possibility to display data from former admission at other neonatal units of transferred patients at actual point of care. Another important benefit of a single configuration for the three systems is to provide the opportunity to merging complete patient admission with identical data row information for data exports. Additional reasons to use a single neonatal PDMS configuration are uniform usability and cheaper interface integration.

A list of some actual commercial PDMS are shown at [Table 01] in section 3.1.4.

The PDMS CareVue original developed sold and supported as CareVue 9000 by Hewlett Packard, Andover, MA is, after interim belonging to Agilent Technologies, now a product of Philips Medical Systems. Many of the people who developed, supported and configured the CareVue product at Hewlett Packard are now employees of Philips Medical Systems. There were many release updates and further developments over years, but the central software has now a lifetime of more than 15 years. The actual PDMS product of Philips named ICIP, former called CareVue Chart, was completely new designed and developed. So there is a definitive limit of using the CareVue "classic" PDMS. Support and further development by Philips will end for the system used at the Vienna general hospital in some years. The decision to implement a new PDMS at the hospital is necessary.

It will be a huge task to replace such a long used and well integrated system with a new one. The data export and interfaces to the additional quality management systems should not be harmed too much by this system change. The concept for the tasks of information retrieval out of the PDMS, described in the main section, shall be flexible and well designed enough to perform for a new system as well. This system change will show if the data export solution concept with its high flexibility can fit the oncoming demands.

5.1 Technical description

The patient monitoring, data devices, computer hardware, network environment, used operating systems and software used at the NICUs are described shortly at this section.

5.1.1 Hardware, Operating Systems and Software

The original name of the PDMS was CareVue 9000 because it was running on HP 9000 Servers. The main business of HP was selling high quality hardware. It was probably the main reason for HP to sell the PDMS and other medical technical systems, like patient monitoring, because those products became more and more a service business.

The software actually used is called CareVue (Classic), which is an ALLBASE/SQL© database application running on HP-UX operating system (which does not meet all UNIX-Standards). The actual installed software release of CareVue (Classic) is I.214.

The PDMS CareVue Application at the AKH-Vienna is currently running on HP B2600 Servers with the operation system HPUX 10.20. The servers are fully duplicated for real hot standby mode. Backup systems and UPS (uninterruptible power supply) are connected to the servers to achieve a high failsafe system status.

Different client PCs are used to run the PDMS application. At bed side two types of Advantec-PCs with integrated display, working without fans and minimal notches and chassis opening for the need of minimizing patient infection risk. A specially released LISCON/LINUX operating system is running on those client PCs.

Beside those bed-side PCs, it is possible for authorized users like physicians to use the PDMS-application at different places not located directly at the ward. That can be lecture rooms, doctor's rooms, research laboratory and others. It is a great benefit that the physicians have access to the complete and actual patient file for medical decisions even if they are not physical present at the ICU.

Those not bed-sided PCs, connected to the PDMS-network, are running Microsoft Windows and start the PDMS CareVue application as a remote "Exseed-XServer" session or as a "reflexion-X" session. To run the PDMS software every single client-PC-system must be configured at the PDMS server application including physically network addresses for security reasons.

Two high quality network printers "HP LaserJet 8100 DN" directly accessed from PDMS-application are located at every unit for patient reports printing.

5.1.2 Interfaces, Network and Patient Monitoring

To handling the interfaces to external devices of the application two MS-Windows 2003 Servers called "MedCom servers" are used. They are configured to manage the input values for patients from different medical devices. The used interface protocols are HL7 and sometimes an easy RS232 data input source. Examples for such external devices automatically delivering data about patients to the PDMS are: laboratory values from laboratory-software, settings from ventilator interface, rates and volumes from infusion pump interface, measurements from the interface of blood gas analyze device and some others.

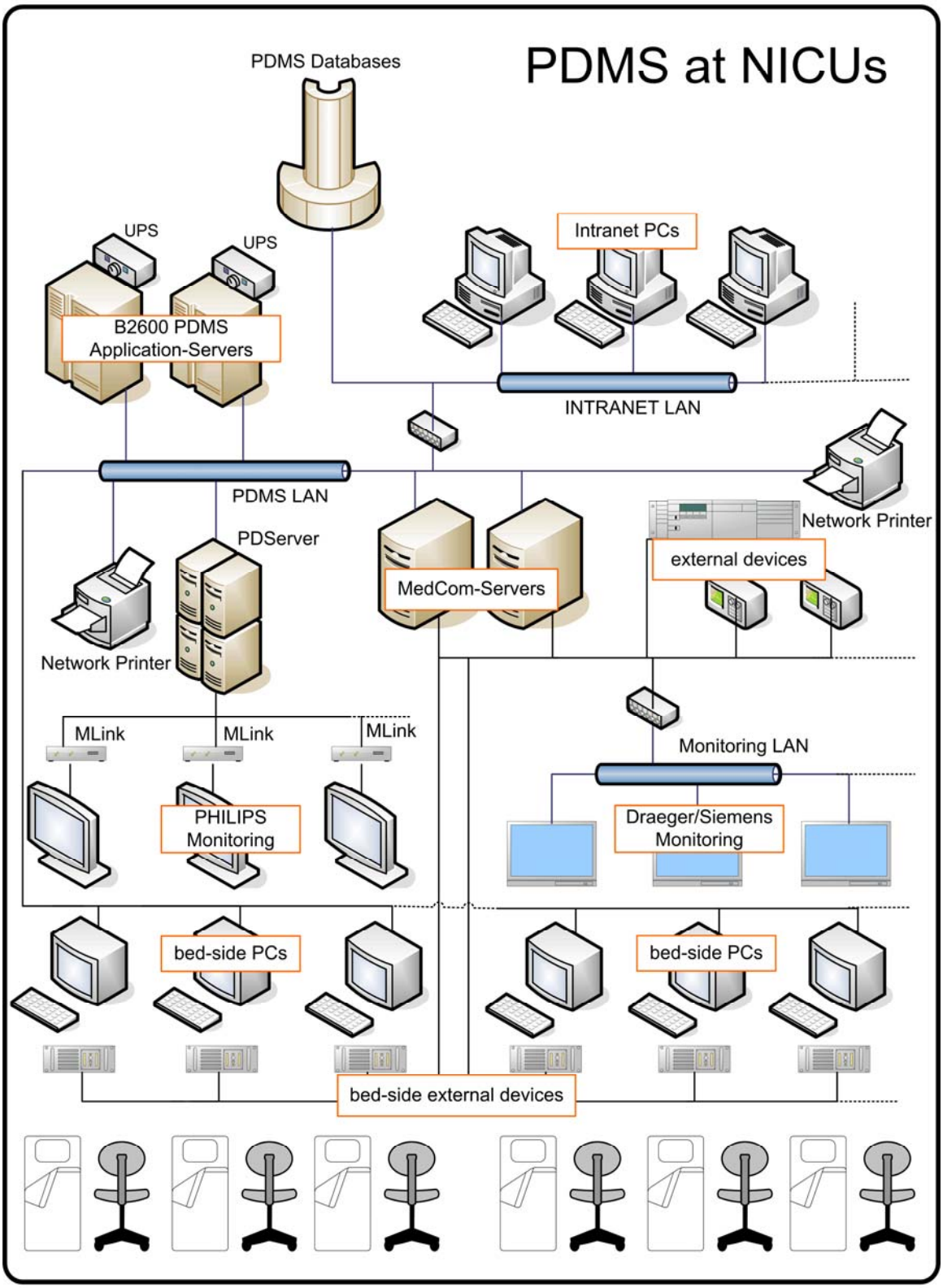
Two different patient monitoring systems are used at the NICUs. The Philips monitoring system is connected to the PDMS using a specific HP Patient Data Server (PDS). The data input uses HL7 standard and receive monitoring data via special MLink-devices [www.mlink.com] to integrate TCP/IP network communication to the server.

The Draeger/Siemens monitoring system is using the mentioned "MedCom servers" to deliver the patient monitoring data to the PDMS application.

System communications und medical device integration is not optimal at the NICUs at the moment. Stability of data communication is high but possibilities to achieve raw data from the integrated medical devices at clear defined port access-points are rare.

The PDMS-Ethernet network with CAT7 cables at the units connects bed side devices, printer, PCs and high performance switches using CAT5 outlets. A separated Ethernet network is installed for the Draeger/Siemens patient monitoring system which is solely connected via "MedCom-server" to the PDMS.

5.1.3 System Overview



[Figure 04]: PDMS at NICU - hardware and network overview

5.1.4 System Reliability

There were no unscheduled system downtimes in the past years recognized at the NICUs. An annual test of the electricity power system of the hospital to check the system stability including UPS (uninterruptible power supply) support was always successful during that time. Of course there are periodical intended system shutdowns for some minutes to update or replace system components. If a new interface to an external device has to be integrated such a scheduled shutdown is used to install the necessary software or configuration.

The complete CareVue “classic” PDMS system with all integrated components is extremely failsafe. This is one of the most required demands to a system for electronically patient data documentation. The PDMS running in the described hospital is reaching this goal perfect.

5.2 PDMS Software configuration

The PDMS was delivered with a basic configuration which was adapted for neonatal requirements using a specific configuration tool. To fit the needs and wishes of the NICU it is necessary first to discuss and define what items in which fields shall be documented and should be displayed. The different experiences with medical paper documentation and computer use of the prospective users lead to a complicate processes to find complete definition of all necessary parameters.

The knowledge of a trained software engineer, with good experiences of medical intensive care documentation, is very helpful for the configuration team. Some physicians and nurses who worked on the process of implementing such a PDMS start a second career as a software configuration engineer. The configuration team consisting of several nurses and intensivists of the NICU was completed by such a configuration engineer who prior worked as intensive care nurse. A computer specialist normally does not know the medical terms and has no idea of the workflow at intensive care. Additional to the definition of the parameters and parameter groups, it is necessary describe formal aspects of every variable such as format, type, dimension unit and contents. Because of user’s paper documentation experience variables are often defined as free text input. It is an important to show the configuration team the advantage of defined selection lists, toggle fields and selection boxes, because that data types will be very helpful at the time of data export for statistical use and quality control.

Implementation of PDMS primarily realizes the demands of bed sided documentation. This kind of using PDMS can be called B-System (bed side), which covers nursing and medical treatment documentation and presentation of vital parameters from patient monitoring and other integrated devices. The second kind of usage at same importance can be called A-System (administrative). This includes patient administration, therapy planning, quality control, outcome statistics and communication to external devices[Heinrichs W., 1998]. The [Table 03] shows an overview about the defined A-System and B-System categories for PDMS implementation demands from that article.

A-System	General documentation demands	examples
	Patient Administration	Admission, Transfer, Discharge
	therapy plans	Medical orders, Diagnoses, etc.
	nursing plans	ToDo-Lists, nursing intervention measurement, etc.
	Quality Control	Scores, infection control, etc.
	Statistic, Outcome, Evaluations	transfer report, ward statistic, etc.
	Connection to external IT Systems	CIS, Lab-System, PACS, Ordering System, Hospital Hygiene, etc.

B-System	Bed-Side-documentation demands	examples
	nursing documentation	Body temperature, events, etc.
	therapy documentation	Medications, stimulations, etc.
	monitoring documentation	Vital parameter, lab events, etc.
	automated documentation from external devices	Patient monitoring, Ventilators, Infusion pumps, Blood gas analyses, etc.

[Table 03]: Overview A-System, B-System from [Heinrichs W., 1998]

Another helpful way to structure the definition task on implementing a PDMS is mentioned in [Fretschner R., et al., 2001]. It defines four levels of action at intensive care. At the normative level the treatment rules are generated and defined. They are based on current state of the art knowledge, clinical practice and controlled trails. These rules are seldom recorded and clear defined, but are essential as common sense of medical treatment. Computerized evidence based guidelines are rare at intensive care clinical practice at the time.

The defined rules are applied to actual patient cases at the strategic level of care and leads to specific medical therapies. At this level the patient data are needed to be displayed in most effective manner to describe patient problems to the physicians as comprehensively as possible. The actions on patient based on physician's orders at the operational level. At that level the therapeutic effects on the patient are measured and recorded. Nurses are primarily working at this task of patient treatment. At the administration level the data of patient and their treatments are joined and recorded. The process to make this information available for quality control is topic of thesis. This data extraction task also provides hospital administration, accounting, and other departments using patient documentation information.

The PDMS configuration tasks to support the implementation process at intensive care are listed in [Table 04]. This table shows the PDMS assistance and, therefore, necessary configuration requirements at the described four levels of action in intensive care.

Level of Action			
ICU		**PDMS**	
action	**persons**	**tasks**	**configuration**
1 normative			
treatment rules	head of department, senior physicians	Guidelines, standardized protocols, CPGs; Exchange of experience: online discussions; Internet intensive care network; Export patient records easily in standardized format;	Guideline integration is not available at current PDMS; (possible with new systems, like ICIP of Philips) No standardized format for patient case discussion is established yet;
2 strategic			
specific therapies	ward physicians, head nurses	Display of patient data: clearly structured; Problem-orientated data presentation: e.g., infection control: Temp., leukocyte count, microbiologic findings, laboratory results, etc. Automated alerts: patient allergies, medication overdose, drug incompatibility, etc.	Overview spreadsheets and forms Anamnesis and diagnostic forms Infection control sheets, trend sheets Medication administration record (MAR) Automated alerts are not available at current PDMS; (possible with new systems, like ICIP of Philips)
3 operational			
measure and record nursing	ward nurses	Display of physician orders; Automated recording: vital parameters, syringe pumps, drip controllers, etc. Data validation; Patient treatment documentation; Automated preparation of patient information for transfer/discharge;	Main task: Parameter definitions; Documentation spreadsheets; Transfer/discharge form; Transfusion protocol;
4 administrative			
processing of patient and treatments data	medical scientists, research nurses, administration staff	Permanent database storage – Datawarehouse; Define Scores: SAPS, APACHE, CRIB, GCS, etc. (physiological, predicting survival) TISS, PPR, (intervention measures); Export patient data to external quality control register databases; Export patient information to hospital administration, accounting, quality control; Export for statistics, studies, etc. Export information to develop and validate CPGs, etc.	SCORE-Sheets Calculated parameter definition: Generated parameters out of existing value-fields; Define counter/fields for missing values; Definition of specific export parameter; No possibility to show information about data export feedback; (possible with new systems, like ICIP of Philips)

[Table 04]: Overview of the four levels of actions in ICU and at PDMS configuration defined in [Fretschner R., et al., 2001]

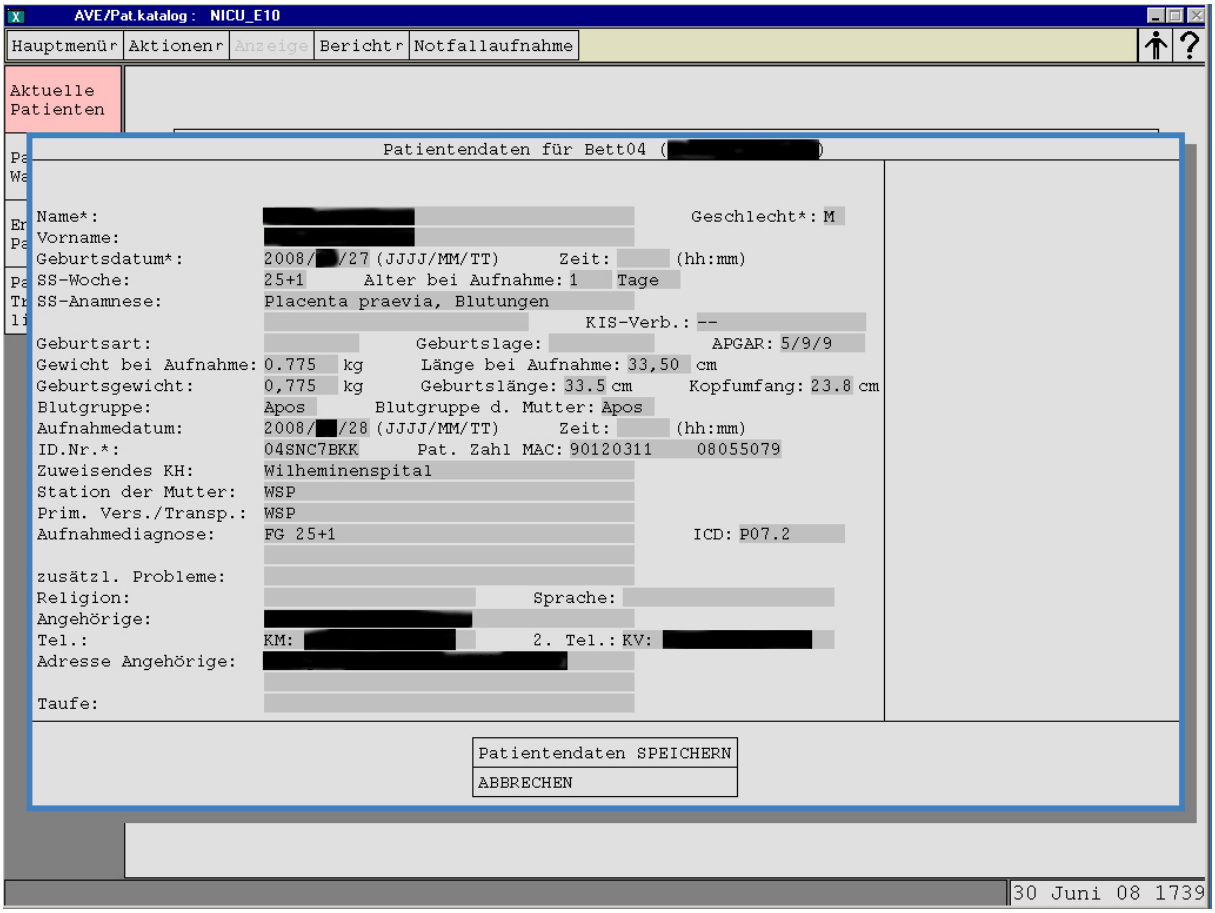
The use of PDMS for quality management at ICUs is part of the administrative level. The solution section will show aspects of this level of actions like defined requirements to fulfill their functions.

5.3 Configuration of the NICU PDMS

The basic software configuration which was delivered with the PDMS had to be adapted by the configuration team. It took about three months work to fulfill that task. The content of a neonatal PDMS differs largely from system for adults. Nearly every parameter ranges, care items, medications, fields for dosage of intake must newly be defined and implemented. Neonatal diagnoses and scores were not included and had to be defined and configured to the PDMS. A complete description of the configuration process at the described NICU and evaluations about the usability of the PDMS at that NICUs were published in [Urschitz M., et al., 1998].

- **Patient administration**

The menu and items for patient admission, discharge and transfer (ADT) planed or urgent are configured and unchangeable. Patient waiting list and transfer list are preconfigured as well. The system provides one patient administration sheet called AVE (patient catalogue). It is the entry form for patient attributes which are needed for patient identification and administration. Only the attribute fields for “patient name”, “date of birth”, “patient sex” and the hospital identification numbers are identical to the adult’s PDMS configuration. All other parameters of the form are configured for special needs of the NICU. For example: “way of delivery”, “gestational age”, “head circumference”, “APGAR-Score” and many more.



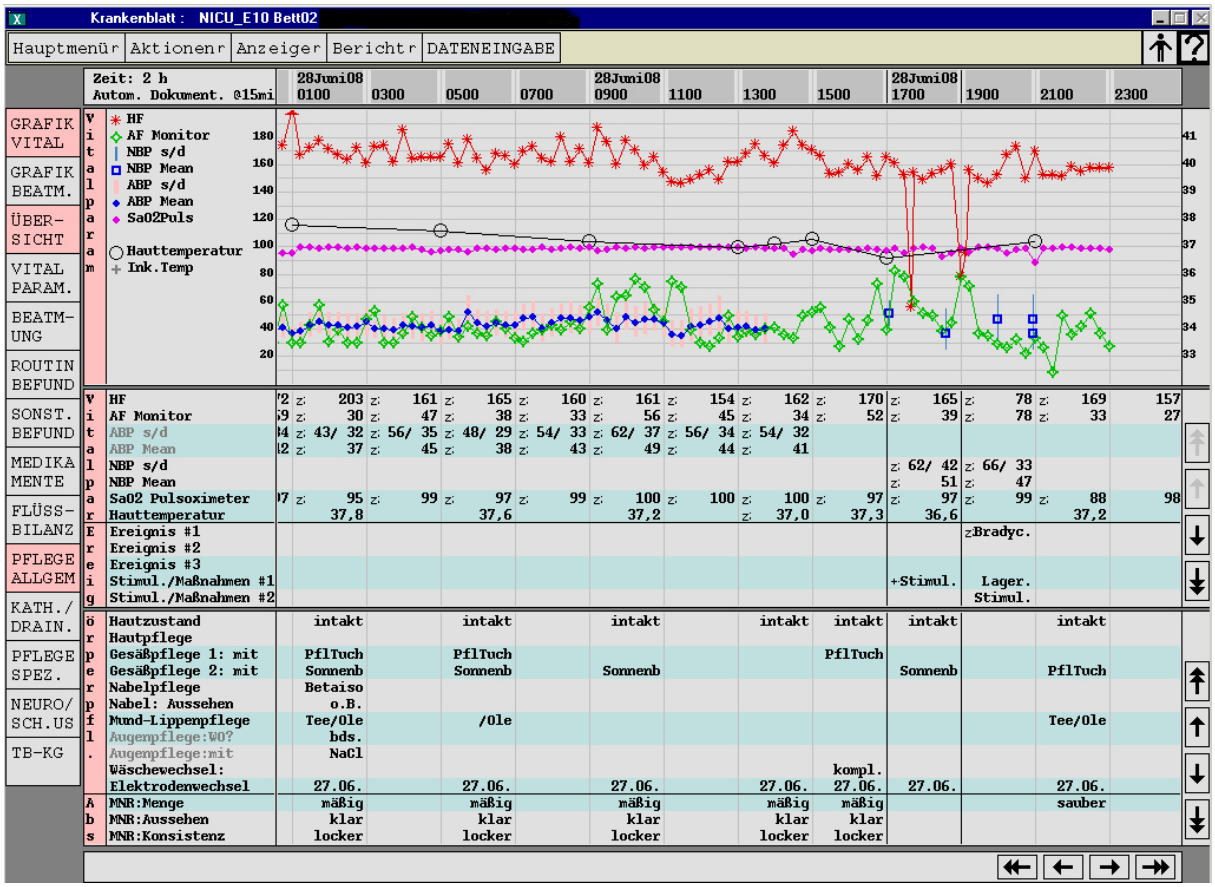
[Figure 05]: AVE-Sheet screenshot form CareVue PDMS at NICU (in German)

- **Spreadsheet documentation**

The time-oriented spreadsheets are the main part for display and for data entry of the PSMS. The timeline can be scaled from exact time, 5 minutes up to 24 hours overviews. Graphic displays of vital and ventilation parameters can be shown in those sheets. All kinds of data types and entry methods are used there. Values for the parameters of those sheets can be entered from a defined pick list as well as automatically be sent from an interface. A list of all types of parameters and possibilities to enter values is shown in [Table 06]. Some parameters can provide two parts of values, like systolic / diastolic blood pressure, or body temperature together with the way it was measured. This causes two data fields for every parameter called value1 and value2 at the PDMS database.

Items entered at such spreadsheet store always two time stamps. The first stamp shows the time when it was entered called [*realtime*] and the second at which time it happened or was measured called [*charttime*]. This is the time at the timeline where the value is displayed. The [*realtime*] must always be after the [*charttime*] with a maximum of 24 hours. That implies values can be entered or corrected up to 24 hours after they were measured. The data entry time and which user entered or corrected the values can be displayed within the spreadsheet.

The spreadsheets are split in different sections which can be displayed by selection to sort logical content [Table 05]. Parameter rows are displayed automatically if any value was entered within a defined time limit. If a parameter is needed to enter data it can be picked from a list of frequently used items or selected out from a logic tree menu. Recently changed or newly entered values are shown in red. The usability of data entry and clearly arranged display of data in such time-oriented spreadsheets is the core part of any PDMS. Several spreadsheets for specific needs can be picked from the main menu of the PDMS. The configuration team defined and implemented such well organized overviews for infection control, nursing, and specific ward statistics.



[Figure 06]: Spreadsheet screenshot form CareVue PDMS at NICU (in German)

SECTION	TYPE	SUBSECTIONS examples
Vital parameters	display	graphic charts
Ventilation parameters	display	graphic charts
Overview	input	vital signs, events, ventilation, blood gas, body balance, etc.
Vital parameters	input	patient monitoring, goals, observations, events, consultations, neurology, etc.
Ventilation parameters	input	events, ventilator settings, checkings, blood gas, etc.
Lab values routine	input	blood count , serum values, urine values, body balance, etc.
Lab values special	input	hemoglobin, bacteriology, homonal, etc.
Drug administered	input	body weight, medication advises, bypass,…

Intake / Outtake – Balance	input	body weight, blood intake, enteral intake, output, total IN, urinary OUT, body balance, etc.
General care	input	general care, body care, extractions, expulsion, nutrition, etc.
Special care	input	surgery, problems, psychological , basal stimulation, etc.
Catheters / Drainage	input	measures, aditus, drains, catheters, etc.
Neurology	input	state, cranial US, etc.
Daily report	input	vital signs, ventilation, blood gas, body balance, events, etc.

[Table 05]: Spreadsheet sections and subsections of the PDMS;

- **Form documentation**

Another important way documenting patient information is the use of configurable forms. The team developed more than 10 specific forms for special documentation. The main difference to the spreadsheets is the absence of any timestamp of the entered values. Every item documented within a form is relevant for the patient at any time. Frequently used forms are anamnesis, status information and special diagnoses forms. Those parameters help to standardize the documentation of medical and nursing diagnoses. The diagnoses entry form helps to document ICD (WHO International Classification of Diseases) coded 9 and 10 digits diagnoses.

- **Note documentation**

It is medical practice to document textual description about patient condition, treatment procedures and important events for every shift. These descriptions are entered by physicians and nurses separately. Such free text documentation, called medical and nursing notes, is difficult to be used for any further automated information processing. It is an easy readable summary for people not used to work with computerized patient documentation systems.

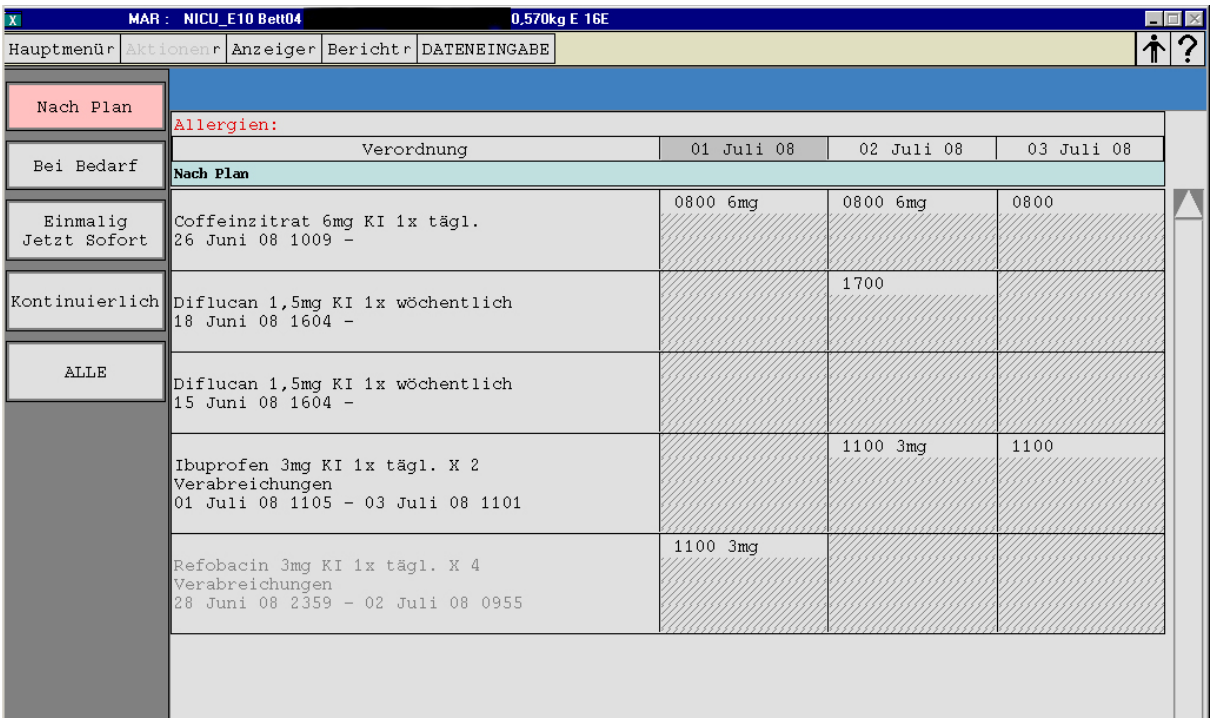
- **Medication Administration Record (MAR)**

The PDMS offers a special method for entering medical, therapy, and working orders. Only very few units worldwide use that feature. There are three forms of working plans to enter medication orders, therapy plans, and a general working plan. It helps to remind nurses to apply frequently medications and other necessary repeated treatment. The reminder stays active until the execution of the order is documented and signed by the nurses. This special functionality of a task list for medical orders of the PDMS did grant a patent:

United States Patent 5072383 1991:
Medical information system with automatic updating of task list in response to entering orders and charting interventions on associated forms:
Abstract:
A hospital information system comprises a data processing system including a plurality of terminals having display means and data entry means. Patient information is entered into the system via the terminals, is organized hierarchically in the system, and may be displayed to users having proper access to the system. The system provides a time-oriented task list, which is automatically generated

from data which has been entered from physicians' and nursing orders. Tasks may be charted by a system user directly onto a system form, and the task list and any associated form(s) are automatically updated.

Documented items of that plans are also displayed at the spreadsheet sections. [Figure 07] shows an overview for several medication orders of a patient.



[Figure 07]: MAR screenshot form CareVue PDMS at NICU (in German)

The possibilities to enter information and data to the PDMS are listed at [Table 06]. These input options are reflected as different data types at specific tables of the PDMS database.

Possibilities of entering data to the PDMS				
input section	**entry type**	**data type**	**charttime**	**corrections**
patient administration	CIS-interface, barcode, manual;	numeric, date, picklist, text;	no	admitted pat.
spreadsheets	all external interfaces: monitoring, ventilators, lab; calculated from other parameters, barcode, manual;	numeric, date, picklist, text; two values; comments on entry;	yes	within 24 h
forms	barcode, from other parameters, manual;	numeric, date, picklist, checkbox, text;	no	admitted pat.
notes	barcode, manual;	text;	yes	within 24 h
plans	barcode, from other parameters, manual;	numeric, date, picklist, checkbox, menu;	yes	within 24 h

[Table 06]: List of possibilities entering data to the PDMS

5.4 PDMS Security

Data security is a fundamental task at any patient documentation system. The highly sensitive information about patient's health shall only be accessible and editable for authorized persons of medical care. PDMS stores information when and who entered or corrected any data for the patient. It is important to know at which time the information was achievable for PDMS users, because they may have to give reason why a specific decision was made. Compared to paper documentation, with electronically PDMS, users will always be suspect to manipulate the data if they are impeached to treat a patient wrong. That is a reason why PDMS offers the function to define complete daily reports of patient information to print. The output can be stored on paper or digital picture archives with picture formats that can not be manipulated.

The documentation system provides procedures to define different user groups with authorization to view or edit data for every unit separately. Patient data or medical orders can only be entered by users with sufficient privileges. Because PDMS displays patient information at point of care permanent, it is not possible to implement automatically user log out functions. It would take to much time to open the necessary screen to display the needed information after required login procedures.

A user who enters data has to sign the entries by entering their password to store them. The view of information at point of care must be fast, but the entering of patient data slows down a bit. The PDMS use at other places at the hospital, like doctor's rooms, can be implemented with an automatically logout process.

Another field of user security is the management of user rights to provide access to patient data at PDMS databases and other digital archives. At the time there is no automatic correlation between these two types of user managements.

5.5 Data quality at the PDMS

The great varieties to document different information types and possibilities to enter patient data lead to a complex structure of data storage. The quality of information and data about the patients can be dependent on the way they were entered to the system. Data from interfaces, barcodes and restrict input masks will normally achieve higher quality. Because of the sensitive and demanding work at intensive care with great time pressure, important patient data can be entered incorrect or not entered anyway by the users. This time pressure is the also reason why only very few mandatory fields can be implemented in PDMS of ICUs. At following sections some problems for information retrieval tasks caused by complex data structures and weak data quality are described.

"*However, as long as there exists no sufficient artefact 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.*" [Metnitz PGH., et al., 1995]

5.6 Keeping PDMS Configuration up to date

A periodical process should be established to keep the PDMS configuration up to date. A multidisciplinary team with members of all involved units and divisions has to define which new parameters are needed or obsolete. For example the configured drug lists must be kept actually. There are necessary frequent configuration changes easily seen by the staff of the units. Some changes of the documentation should be done because patient data are used for newly implemented systems which are connected to the PDMS database. Those systems may need specific parameters which are not documented yet. That additional documentation of patient data with no direct benefit for the units must be explained to the users. They must understand the necessity of those parameters for other reasonable tasks of medical data processing which may sometimes be difficult to be shown.

All changes of the PDMS configuration should be done carefully and well planed because the users need to be trained to use the changed patient documentation correct. If users of the system do not know why and how patient data should be documented and do not recognize the necessity of doing that, the quality and completeness of the data will be weak. That can cause the use of those patient data for additional quality management systems to be nearly impossible.

5.7 PDMS Databases

Patient data are stored together with configuration information at the ALLBASE/SQL© database of the CareVue “classic” application. Some time after the patient is discharged from the system of a unit the data are purged from the application database. When patients are transferred from a system (equal care unit) to another system their data are copied to the destination system to be reachable there.

- **PDMS “DBExport”**

The only possibility to export, or even excess patient data without the CareVue-application, is the execution of HP-UX system internal database (IDB) queries. That “interface" (IDB) provides extracted data in up to 22 ASCII files. To communicate with the PDMS and execute the IDB queries, a DOS program, running with MS-Windows NT, called “DBExport” must be used to generate the delimiter separated ASCII files with the wanted patient data export. Those files can be used to transfer some patient data from the PDMS to other IT systems.

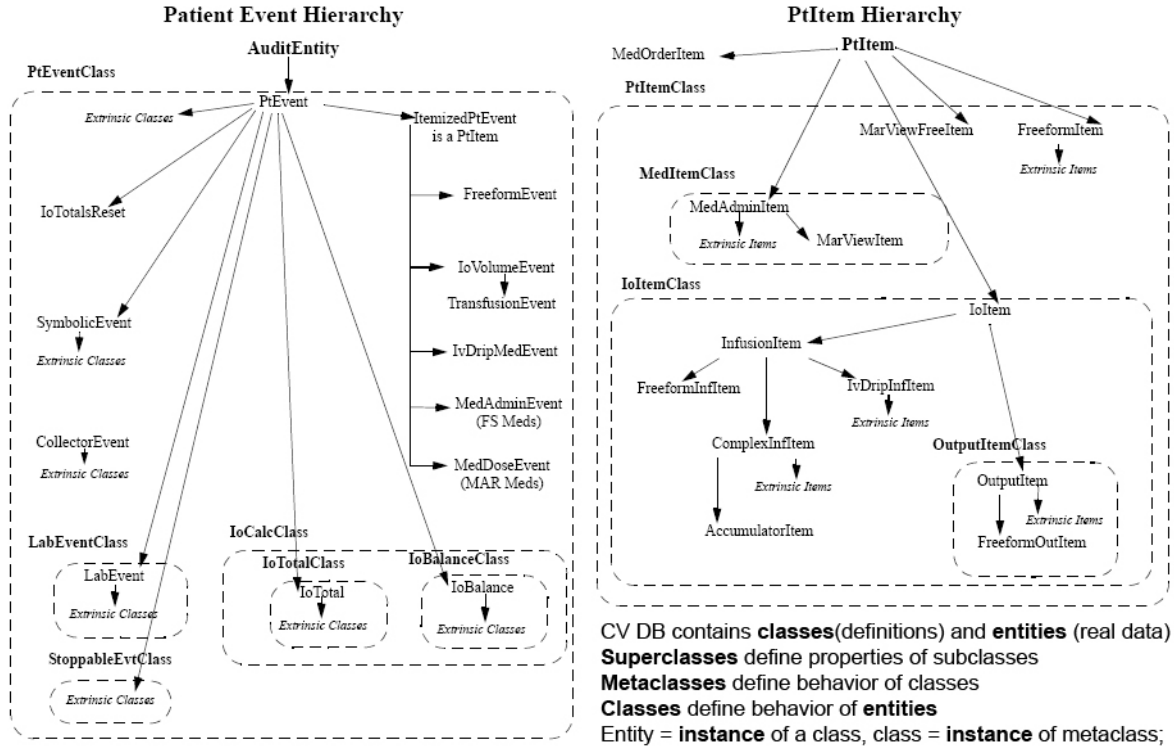
This PDMS exporting method is limited and very uncomfortable. The time needed by those data export processes is hardly calculable. No explicit database indexes can be used by the export queries. Because the process executions of the PDMS application is of higher priority than any data export processes the system may need rather long time to generate any output. The most important disadvantage using “DBExport” is the risk to slow down the PDMS CareVue application at point of care. This potential, but seldom, system reactions should avoid the regularly use of that data exporting method.

- **Clinical Data Archive (CDA)**,

In 1997 the Clinical Data Archive (CDA), a patient data acquisition and storage management system of the PDMS was installed. The CDA acquires and stores patient data from multiple CareVue point-of-care charting systems. The acquired patient data is archived within the CDA database indefinitely, long beyond a patient's hospital encounter. This long term patient data storage capability creates an immense "data repository" of patient information that becomes resource for projects using data from the PDMS patient documentation. All patient data archives are maintained across potential changes in CareVue system configurations and software revisions.

The CDA system includes an ODBC interface to the CareVue application, a data extraction and consolidation engine, an Oracle based clinical repository and a tool set to enable ongoing management of the database. The CDA database schema closely reflects the CareVue ODBC schema. The CareVue ODBC driver flattens the object-oriented CareVue database into a relational database model. As a result, the CDA schema is not optimally tuned for relational queries and may appear overly complex or bulky in some areas. The CDA schema has added tables and table attributes to correlate patient data collected over time, across multiple data sources and across different database schemas. Consolidation of data from multiple and changing CareVue source databases requires that keys, schema versions, and configuration states are generalized on the target CDA Oracle database.

The CareVue database has been developed using an object-oriented model. This database cannot be queried with standard SQL. It is necessary to understand the structure and rules of the CareVue database and how this object-oriented database has been mapped to a relational database.



[Figure08]: Hierarchical CareVue Database Schema used at CDA

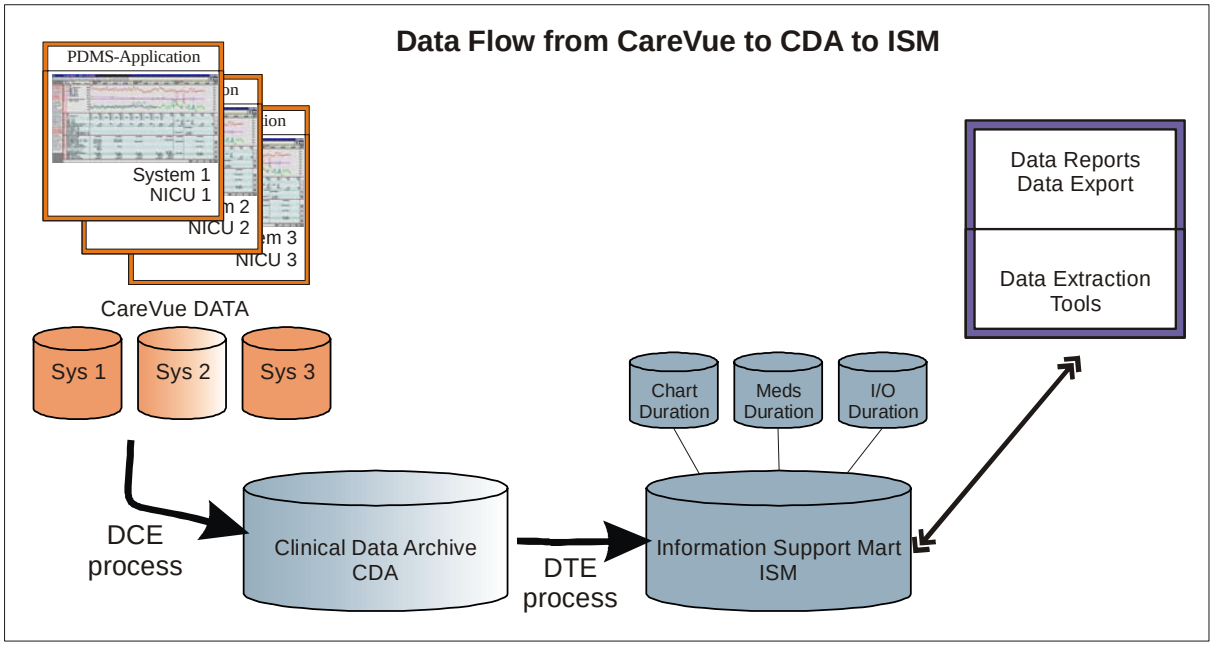
- **ISM (Information Support Mart)**

In 2000 the additional PDMS database schema ISM (Information Support Mart) was implemented. Together with the CDA the system to access CareVue PDMS data is called CDM (Clinical Data Management) system. The ISM works in conjunction with the CareVue CDA to provide an interface to the CareVue data. Some PDMS data are not accessible at the ISM database schema. All of the CareVue configuration and system information has been removed in the ISM schema. Password and other security information are not available at the ISM. To simplify the ISM schema, the audit trail for corrections is not maintained in the ISM. Only the final charting for a particular time is retained.

The structure of the ISM data mart is based on a star schema which has the “FACTS” of the patient data in the center of the star and the “DIMENSIONS” of the patient data as the points of the star. The ISM database structure uses 18 fact tables, 13 dimension tables and 3 duration tables. 27 tables store information to link ISM information to the corresponding CDA data.

The CDA is a long-term archive of all data gathered from CareVue systems and consolidated in a single database that mirrors CareVue's 300 tables. Its role is to provide a single database that can hold all data for typically 3 years. To querying it considerable understanding of CareVue's database structure is required.

The ISM database provides a long-term archive as well, but it holds patient data in only 30, rather than 300 tables. It gets its data from CDA and has been designed to run on the same hardware as the CDA database. Its role is to provide easy access to the patient data and therefore it has a totally different database schema from CDA schema. The ISM schema represents a highly denormalized view of the clinical data elements.



[Figure 09]: CareVue Database ISM Concepts and Data Flow

DCS Process: Data Consolidation Engine. Used by the CDA to extract CareVue data.
DTE Process: Data Transformation Engine. Used by the ISM to transform the CDA data.
Duration tables: Individual database tables which contain information describing the length of time a particular item has been used.

Because the ISM schema uses CDA as data source the data values for export are accessible slightly sooner at the CDA schema. Depending on the needed information and patient data and time relevance it must be decided which PDMS database schema should be used.

For information about the CDM, CDA, ISM and the descriptions about the structures and figures the documents [CDA Manual, 2000] and [ISM Guide, 2001] were used.

5.8 Quantity and quality of data at PDMS databases

The data volume stored for all systems and the NICU and the quality of the data in the PDMS databases, listed by category of patient information, are presented at the next tables.

[Table 07] shows the data volume of the CDA and [Table 08] of the ISM data schemas of the PDMS database for all connected systems and the NICU systems, stored in some typically patient data and metadata tables. The partitions of NICU data of the overall data volume differ between the tables holding varying categories of patient information from 2% up to 70 %.

	ALL UNITS	NICU 1	NICU 2	NICU 3	ALL NICUs	
duration(years)	4,37	4,35	4,23	3,09	4,35	
CDA						
cfgpatients	patients admissions					
# rows	407.110	2.335	6.047	770	9.152	**2,25%**
censusevent	admission, transfer, discharge events					
# rows	1.027.572	5.314	8.510	3.944	17.768	**1,73%**
ptevent	charted patients values; vital parameters, ventilation, etc.					
# rows	715.825.480	20.957.881	17.457.897	13.860.928	52.276.706	**7,30%**
labevent	charted patients laboratory value					
# rows	40.468.620	715.379	610.375	341.293	1.667.047	**4,12%**
iovolumeevent	patients intake/output values					
# rows	17.847.590	937.126	697.967	622.144	2.257.237	**12,65%**
pteventclass	configured event items					
# rows	107.094	1.184	1.184	1.184	3.552	**3,32%**
labeventclass	configured laboratory items					
# rows	12.065	254	254	254	762	**6,32%**

[Table 07]: Data rows at tables of CDA DB schema for NICUs and all systems

	ALL UNITS	NICU 1	NICU 2	NICU 3	ALL NICUs	
duration(years)	4,37	4,35	4,23	3,09	4,35	
ISM						
d_patients	individual patients					
# rows	135.628	1.004	2.182	466	3.652	**2,69%**
censusevents	individual patients admissions					
# rows	257.561	1.242	2.291	583	4.116	**1,60%**
chartevents	charted patients values					
# rows	402.895.608	13.783.376	13.031.848	6.256.518	33.071.742	**8,21%**
medevents	patients medication events					
# rows	8.596.863	318.646	153.721	182.303	654.670	**7,62%**
totalbalevents	charted patients intake/output totals and balances					
# rows	4.931.102	199.758	150.960	149.654	500.372	**10,15%**
d_chartitems	used charted item parameters					
# rows	29.517	1.234	961	804	2.999	**10,16%**
d_meditems	used medication item parameters					
# rows	3.207	1.109	630	596	2.335	**72,81%**

[Table 08]: Data rows at tables of ISM DB schema for NICUs and all systems

At [Table 09] the average numbers of data rows at fact tables of the ISM-Schema for a single patient are presented. To measure that average date volumes 203 patients of one NICU at duration of 1 year were analyzed. The distribution of patient data volume at the different fact tables is very unbalanced. Nearly 90 % of patient data rows are stored in one single table used for charted spreadsheet information.

NICU 1	**ISM schema**	
1 year	duration	
203	patients	
average rows per patient		**percent**
24126,34	charted standard spreadsheet rows	**89,822%**
559,65	medications	**2,084%**
93,47	medication orders	**0,348%**
1108,83	I&O events	**4,128%**
448,72	I&O total, balances	**1,671%**
181,11	charted additives	**0,674%**
42,14	Charted deliveries	**0,157%**
56,95	Charted solutions	**0,212%**
115,56	charted event from forms	**0,430%**
126,03	charted notes	**0,469%**
1,30	admission events	**0,005%**

26860,12	**total**	**100%**

[Table 09]: Average rows at fact tables of ISM DB-schema for one NICU

The data quality of patient admission information and parameters needed for patient identification at the ISM and CDA database schema is shown at [Table 10]. One year of patient data from one NICU are measured and analyzed at that table.

NICU	**patient admission identification**	
	duration	1 year
ISM	admissions	557
	no entries	**9,69%**
	adm. shorter 10 minutes	**2,51%**
	invalid patient record number	**4,67%**
	invalid patient adm. (dob)	**1,44%**
	identifiable adm.	**81,69%**
CDA	admissions	534
	no entries	**10,49%**
	invalid patient record number	**4,49%**
	missing/invalid birthweight/GA	**5,62%**
	identifiable adm.	**79,40%**

[Table 10]: PDMS data quality of patient identification parameters at ISM and CDA

About 15 % of the patient admission at the PDMS of the NICU can not be identified automatically. With some additional data validation methods this identification rate can be improved to 90 %.

PDMS documentation items, entered to the system, using integrated machine interfaces and manually input with validation masks, are measured at [Table 11]. The patient data from one NICU is presented at that table. PDMS data were taken from the CDA database schema.

NICU	**patient parameter values**	**CDA schema**
	duration	100 days
input	**monitoring interface**	
	HF (heart rate)	n=86437
	valid	**99,67%**
	plausible	**99,52%**
	SaO2 pulse oximeter	n=100614
	valid	**99,99%**
	plausible	**99,80%**
	duration	300 days
input	**manual with validation mask**	
	body temperature one value	n=9481
	valid	**99,19%**

	plausible	**99,01%**
	body temperature value and method	n=10655
	valid	**99,81%**
	plausible	**99,61%**
input	**laboratory interface with user interaction**	
	blood gas: base excess	n=3958
	valid	**87,39%**
	plausible	**87,34%**

[Table 11]: PDMS data quality of patient items of different input types at CDA

The manual data entry was done using pick lists and numeric scrolling input fields with range checks. The density of measured values from interfaces is much higher, but the data quality can be slightly poorer than manual parameter value input. Values from the laboratory interface entered manually there and send by users to the PDMS perform worst data quality at this measurement.

Restrict data input with validation checks raises data quality. Such restrictions can only be used very rare, because of the before mentioned time pressure at intensive care. Extracting data from such PDMS database must consider the sometimes poor data quality. Specific data validation methods and automatically correction methods should be used by the data export processes.

6 Quality Management-Systems (QMS) at the NICU

IT applications at the NICU used for quality management run on several different system environments using separated network. There are systems with front end applications and scripts running on the PDMS equipment which can be used at point-of-care. Other systems used to control and improve quality of patient treatment are running on separate “scientific” environments of the Medical University Vienna. These systems are connected to the internet and must handle security options for patient information involved. The environment for CIS and other HIT for routine work at the hospital is used by such QMS at the NICU as well.

The QMS described in this section are connected directly or have any possibilities to access data from the PDMS database. Especially for systems running on the environments of the Medical University additional task for data and information transfer are necessary to fulfill patient data security.

The focus in this section is the recommendations and premises for the export of patient information for QMS at the NICU from the database of the PDMS. This exported patient data are located on the PDMS environment. Any further process to access this generated specific information by any QMS application used as front end will not be pictured in detail. The main challenge is to show methods and procedures to transform and export patient information from the PDMS database required by the used QMS. Most of the systems for QM have specific applications and settings which can be configured for proper access to the generated information from the PDMS.

The solutions for information retrieval from the PDMS database are described without additional explicit adaptations for the specific requirements of the applications used as front-end for QM at the unit. To view and compute the retrieved information for QM from the PDMS some systems use MS-EXCEL application.

6.1 Premises and Recommendations for QMS using PDMS data

There are some essential premises for any successful information retrieval from the PDMS/CIS database for any QMS. Only if every condition for the data export is defined and can be met by the export procedure the implementation makes sense. It can be difficult and sometimes impossible to find all necessary definitions and requirements of the needed data and information for a QMS. But any solution of the patient data reuse can only be correct and lead to effective quality management, if all qualifications needed are fulfilled. Sometimes convincing and some work for the involved clinical and administrative staff are demanded. It should be considered that quality control and management can only be done with correct data and information about the patient.

Premises and recommendations for QMS using patient data from the PDMS:

Definition of the **patients** whose data are needed for the QMS:	
Premises	
	Criteria for patient type – attributes: Exclusion and Inclusion criteria of patients definitions
example:	Birth weight must be lower than 1500 gm Specific problem or diagnoses
	Criteria for patient admission: Patient identification numbers which are required Minimum/Maximun admission time definition
example:	Patient must be admitted for more than 1 hour
	Readmission handling definition
example:	When patient readmitted within 12 hours data must be linked.
	Discharge/Transfer definition
example:	Patient must be discharged home
Recommendations	
	Define additional patient information for identification:
example:	Sex, data of birth, multiples birth, birth weight, etc.
	Define Patient admissions status: Every possible admission, transfer, readmission and discharge status.
Definition of the **data** and information of patient required for the QMS:	
Premises	
	Data type: For each wanted parameter the value format must be defined
example:	numeric (99.99), text (length 30), selection (1,2,3,4), boolean, etc.
	Data calculations: For each wanted parameter the criteria of selection of specified time period must be defined
example:	maximal Heart Rate (HR) within data range ventilation type of day: if multiple types were applied selection criteria must defined like: prioritization or type used the longest time of day
	Data density: Definition of required density for vital parameters or other measurements
example:	continues blood pressure measurement is required body temperature measurement at least every 4 hours required
	Data conditions: Definition of parameter for export to set true under specified circumstances and qualifications for specific parameters to export.
example:	If patient is VLBW and initial Base Excess (BE) < -5 set parameter high-risk TRUE Export catheters documentation if patient infection_risc parameter > 2
Recommendations	
	Data range: For each parameter define the possible ranges of the values: Normal-range; Plausibility-range; Technical-range;

example:	blood hematocrit (neonatal): normal 37-55, plausible 10-85, technical 0-99; number of echocardiography examinations: normal 0-2, plausible 0-4, technical 0-9
	Data rules: For each parameter define the complete rule to meet all conditions for export.
example:	respiratory support of day for NeoTISS-Score: Choose maximal support supplied: if any oxygen applied (1), if any CPAP including nasal applied (2), if mechanical ventilation without relaxation (3), if mechanical ventilation with relaxation or High-Frequent-Ventilation (HFOV) (4);
	Data density: For each parameter with calculations or statistic adaptation (minimum, maximum, ratio, median, etc.) or used for scores: define conditions for the time interval required to receive the correct result.
example:	Maximal serum base excess (BE) for CRIB of first 12 hours after admission: Measurement must be done at least twice and first within 3 hours after admission.

Definition for **technical** environments of the QMS:

Premises	
	PDMS-database: The database with the patient data of the PDMS/CIS must be reachable with some tools for data export and scripting. It must be possible to import the results and exported values to the QMS.
	Performance: The performance of the data export process, further calculations and processing and the interfaces needed and used by the application must reach the required time borders for the QMS.
	Technical Equipments: Patient monitoring, Lab-systems, networks, PC workstations and servers, backup systems, operating systems, application platforms, etc.; All involved technical systems must be adequate for the QMS and demanded data export processes.
	Interfaces: The technical feasibility to use and deal with interfaces and data export is required for the QMS. Any data import routines, configurable connectivity to data sources using interfaces is essential for the system.
Recommendations	
	Additional interfaces to other data sources using standards, like HL7
	Possibility to access the Hospital Information System (HIS) for calculation and survey of the complete patient admissions in the hospital, because some information from this system can be consequential after discharged from the ICU.

Definition for the QMS **software** and user front-end:

Premises	
	Display errors: It must be possible to display errors appearing during the data export processes.
	Correction/Add data: The system must have any possibility for users to correct or add important missing data received incomplete or wrong from the PDMS/CIS export routine.
Recommendations	

	Display messages: The system should offer any user interaction process to show problems like data range validations or undefined patient classifications from the data export and other information from the data exporting routine.
	Configurable data import interface: A configurable, easy to use, interface to configure the data import facilitates for QMS integration is recommended.
	Data validation: Tools or processes and functions of the QMS-software for automated data validation during import or on demand are very valuable.

[Table 12]: Quality Management System premises and recommendations

If all premises and some recommendations to use the PDMS/CIS of the unit as source of patient information for the QMS mentioned in [Table 12] are achieved, the implementation of the data export process can start. This process can be successful if some of the clinical and administrative users have the knowledge about the aim of the system used for QM. The chance to succeed will rise if there are clear advantages for medical work at the ICU. The interests to use such QM system at the unit are often mainly intended by the leading staff and institutions for quality control and strategic planning. The implementation of such data export is a time and resources consuming interdisciplinary team approach, so it is necessary that sufficient personal resources can be provided by the involved persons. The interest to use such systems at the unit helps to motivate physicians and nurses to be integrated during the implementation and to support the process with their knowledge and experience.

A protocol to define all differences between reused information for the QMS and patient data routinely documented at the PDMS should be generated during the implementation process. A feedback circle to evaluate the export routine and to keep the system actual should be established as soon as possible. It should be made clear that the integration of a QMS to the routine work at the unit will be a task for a longer developmental period.

6.2 Data and information not found at PDMS

If some information needed for the QMS can not be found directly in the database of the PDMS different solutions for that problem are possible. The following order to get the needed information is recommended:

(I) Check if the information can be calculated from available data.
Some information can be found by combining data and information documented in the PDMS. That can be a rather easy calculation to get the necessary unit of measure or a real complex crosschecking routine of many fields of the database. All involved data to calculate the

information should be documented, to keep in mind, that there are dependencies and any change in using or reconfigure them affect the result needed by the QMS.

(II) Check if the information can be received from other data sources:
Any other system, like laboratory software or HIS with patient data that can be achieved via interfaces are a potential source for the QMS. It would be the best method to integrate those sources directly to the PDMS, because the data can be used by other system connected to the database as well. Otherwise an additional procedure for patient identifications and data linking is necessary for the extra interface. This would lead to complex system interdependence and maintainability.

(III) The information must be additionally entered to the PDMS:
If the information required for the QMS can not be found in any existing data sources, they must be additionally entered by the users. It should be preferred to configure the additional data fields to the PDMS, because other connected systems will get the possibility to use as well. This postulate, that the needful information must be entered by the clinical users at the ICU. Therefore, the users at the unit need to have the information and must have time and will to enter it for the patients. So in some last cases it may be necessary to use a special interface of the QMS to enter the data directly into the system. Avoiding that last solution would help to keeps the complete system behaviors more easy and maintainable.

The risk to accept worse quality of data and information is rather high, because of the additional expenditure to get the correct information about the patients. Depended of the importance of the information it is necessary to considerate the risks and benefits individually for every needed item. It should be kept in mind that the quality of the QMS is controlled by the quality of the used data and information about the patients.

6.3 QMS applications at the NICU

Applications for quality management, quality control and cost accounting implemented at the NICU are used for several tasks including

- generating ward statistics
- single patients' and problem-oriented data reviews
- joining external quality management systems
- supporting medical studies and research projects
- develop and validate ward specific protocols and guidelines
- gathering cost relevant patient and treatment information
- infection monitoring
- calculating the parenteral nutrition
- visualization of patient's condition changes
- supporting optimal ventilation

6.3.1 External quality benchmarking

Established scoring systems should be used for external and internal quality control at intensive care. The Austrian ASDI intensive care data set [www.asdi.ac.at, 2008] including a benchmarking project and the international Vermont Oxford Network database [www.vtoxford.org, 2008] are well approved and widely-used systems. The NICU is member of both institutions and use the benchmarking reports for quality management for a long time.

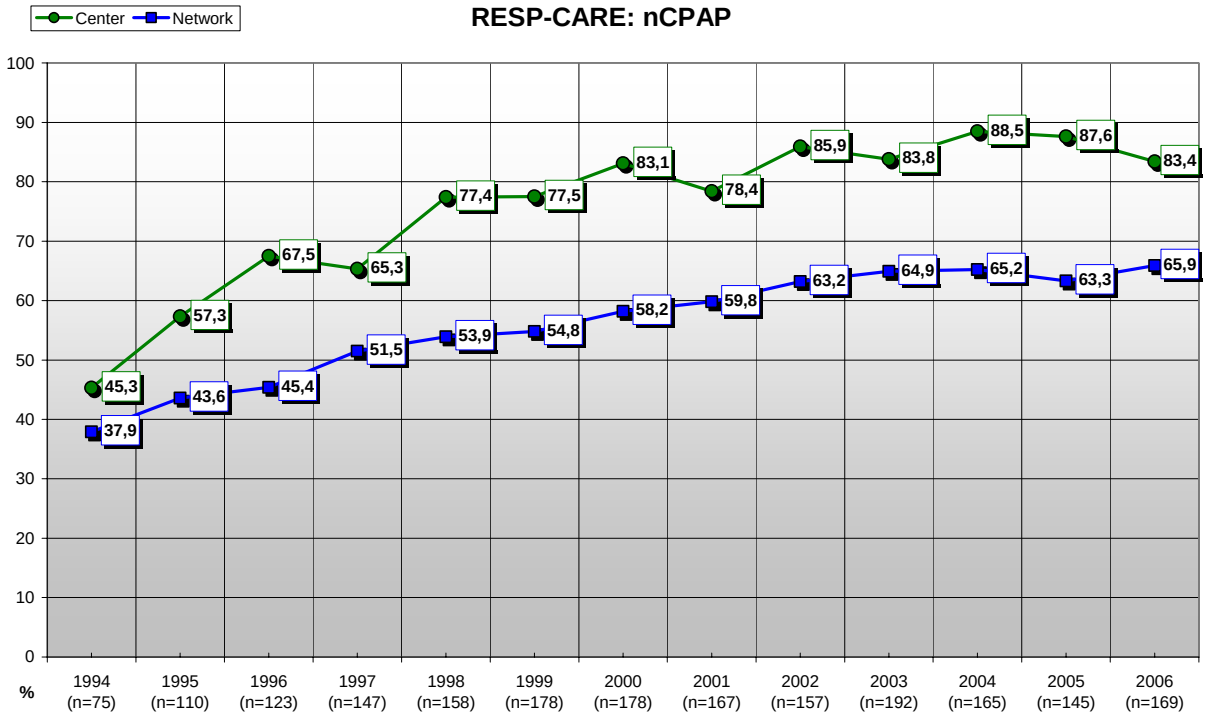
Since 1994 the NICU uses the Vermont Oxford Network (VAN) as quality management tool and research background for babies with very low birth weight (VLBW) between 401 and 1500 grams. At the time, the required data of more than 55.000 vlbw infants from more than 700 NICUs world wide are uploaded to the network every year. Electronically data submission to the VON database is provided since 2000. The collected data of more than 150 vlbw babies treated at the NICU are uploaded in the defined data structure every year. Data validation is done during export and by special validation and crosschecking rules after submission to the network. Errors and warnings reports from that validation checks are generated and sent back to the unit.

This long term data pool supports quantification and benchmarking of treatment at the NICU over years. Many outcome parameters of the NICU in relation to all network units can help to show and control the performance of care at the neonatal-perinatal medicine of the hospital. An example is shown in [Table 13] and [Figure 10] analyzing the use of nasal CPAP as respiratory care at any time of the patient admission by birth weight in 2006 and over the years.

Respiratory Care - All VLBW Infants: **Nasal CPAP**								
	Center (2006)				**Network (2006)**			
Birth Wgt 10 Levels	**Cases**	**N**	**%**		**N**	**%**	**Q1**	**Q3**
< 501	0	0			1071	**35.0%**	0.0%	57.1%
501-600	4	8	**50.0%**		239	**51.1%**	0.0%	73.7%
601-700	10	16	**62.5%**		3639	**64.7%**	33.3%	81.8%
701-800	13	13	**100.0%**		4151	**73.5%**	50.0%	100.0%
801-900	15	17	**88.2%**		4263	**78.5%**	63.6%	100.0%
901-1000	20	20	**100.0%**		4540	**78.0%**	59.2%	100.0%
1001-1100	16	17	**94.1%**		4585	**76.0%**	61.7%	100.0%
1101-1200	16	18	**88.9%**		5039	**70.2%**	50.0%	90.9%
1201-1300	14	16	**87.5%**		5284	**64.9%**	44.4%	84.6%
1301-1400	16	23	**69.6%**		5852	**58.8%**	37.5%	80.0%
> 1400	17	21	**81.0%**		7103	**53.6%**	33.3%	71.4%
All	141	169	**83.4%**		47917	**65.9%**	50.3%	76.9%
	Center				**Network**			
Year	**Cases**	**N**	**%**		**N**	**%**	**Q1**	**Q3**
1990					2909	**35.3%**	4.4%	59.1%
1991					3819	**34.1%**	9.8%	60.7%
1992					4953	**33.1%**	7.0%	58.4%

1993				6503	**35.6%**	9.5%	58.8%
1994	34	75	**45.3%**	8191	**37.9%**	17.0%	57.5%
1995	63	110	**57.3%**	10702	**43.6%**	20.8%	63.2%
1996	83	123	**67.5%**	14672	**45.4%**	23.8%	63.7%
1997	96	147	**65.3%**	19567	**51.5%**	33.3%	66.7%
1998	123	159	**77.4%**	23622	**53.9%**	37.0%	68.1%
1999	138	178	**77.5%**	26278	**54.8%**	42.3%	68.7%
2000	147	177	**83.1%**	29119	**58.2%**	47.1%	72.0%
2001	131	167	**78.4%**	30043	**59.8%**	48.3%	72.7%
2002	134	156	**85.9%**	32034	**63.2%**	50.7%	73.2%
2003	160	191	**83.8%**	34984	**64.9%**	53.0%	75.4%
2004	146	165	**88.5%**	40322	**63.9%**	51.4%	75.0%
2005	127	145	**87.6%**	44003	**63.3%**	48.8%	74.8%
2006	141	169	**83.4%**	47917	**65.9%**	50.0%	76.9%
2007	126	161	**78.3%**	51813	**66.1%**	51.4%	77.6%
2008	79	106	**74.5%**				
All	1728	2229	**77.5%**	431480	**59.2%**	44.9%	71.1%

[Table 13]: Nasal CPAP use at the NICU and Vermont Oxford Network



[Figure 10]: Nasal CPAP use at the NICU and Vermont Oxford Network by years

The specific data of the NICU over years together with that long term VON database are a collaborative information source for medical research and projects for evidence-based treatment reviews. For example the research and authoring of the article *"Is the use of early nasal CPAP*

associated with lower rates of chronic lung disease and retinopathy of prematurity? Nine years of experience with the Vermont Oxford Neonatal Network." [Kirchner L., et al., 2005] was done at the NICU.

6.3.2 Ward statistics

For specific ward statistics of the NICU the data structure and concept was developed in 1987 as a SAS/WAMASTAT application running on mainframe IBM – server with VM/CMS operating system. In 1993 a more comfortable user interfaces was added for easier data input. The SAS application was moved MS-Windows operating platform later. A lot of data and information about patient admissions were entered by many busy users. The system can generate ward specific statistical information and output from the early eighties until now. The system was developed and is maintained mainly by Manfred Weninger, chief physician of the NICU, and Ernst Eigenbauer, member of "Medical Information and retrieval Systems" department of the Medical University of Vienna, as technical consultant.

The applying data and information of the patient admissions for the ward statistics are collected and summarized with the PDMS. They are entered with a specific SAS interface especially designed for the NICU needs by administrative users. Entry checks help to get valid and completed data sets for the statistical calculations and outputs.

6.3.3 "Scientific Database"

A long term quality control database called "scientific DB" was set up in 1997 at the NICU. The database was expanded with prenatal information in 2002 and held such patient data since 1999. An expansion of the DB with information and data of patient aftercare until the age of 12 years is on going. Expanding that database created some additional problems caused by complex patient admissions identifications. Information and data about patient's mothers must be linked to the babies who often are delivered by multiple births. There is an additional validation problem because diagnoses, applied therapies and treatment problems at other departments can only be checked by clinicians working there.

The intention was to designing a database tailored to the needs of data analysis which can be used for improved data evaluation with enhanced possibilities of data management. The parameters of the database are grouped by the time they are assessable for medical users:

- before admission: information about the mother prenatal information, etc.
- at admission: administrative, perinatal, prenatal information, etc.
- 12/24 hours after admission: physiological condition, initial treatment, etc.
- daily data: ventilation day, vital parameter summaries, interventions, etc.
- at discharge: outcome (IVH, PVL, etc.), weight, nutrition, etc.
- after discharge from NICU: problems of child, diagnoses, etc.

Each parameter is defined according to its data type range (normal, possible, plausible), default values (nothing was elevated) and required measuring unit. Examples for the definitions of some parameters of the "scientific database" are shown at [Table 14].

	LENGTH at Admission	initial pH venously	initial pCO2 venously	initial BE venously	initial Bicarbon at	initialer BZ	VBG Hour of life	Intu-bation (<12h)	Intub. Hour of life
Calculation	BL	pH_v	pCO2_v	BE_v	HCO3_v	BZ_v	ROUND (time,hh)	Intubation	ROUND (time,hh)
time of measure	FIRST	FIRST	FIRST	FIRST	FIRST	FIRST	FIRST	<12h	FIRST INTUB
rowname	bodylength (cm)	VBG: pH	VBG: pCO2	VBG: BE	VBG: SBC	Glucose S	VBG: pH	Ventilation : airway	Ventilation : airway
section	Pflege allgemein	Beatmung Blutgase	Beatmung Blutgase	Beatmung Blutgase	Beatmung Blutgase	Routinebe fund	Beatmung Blutgase	Beatmung	Beatmung
unit of measure	cm		mm Hg	mmol/L	mmol/L	mg/dl	hours		hours
TYPE	ZZ	Z,ZZ	ZZ	Z/-Z	ZZ,Z	ZZZ	HH	J/N	HH
min	10	6	10	-30	1	1	0		0
max	60	8	150	30	50	500	12		12
normal range	28-52	7,2-7,4	30-80	5 bis -5	18-30	35-120	0-12	N	0-12
pathological	<28 >52	<7,2	<30 >80	<-5 >5	<18 >30	<35 >120		J	
SOURCE	Care Vue	Care Vue	Care Vue	Care Vue	Care Vue	Care Vue	Care Vue	Care Vue	Care Vue

[Table 14]: Definition of patient parameters for the “scientific database” (partly German)

At the time about 1400 vlbw patients from 1999 to 2007 are stored in that database. All calculated patient data needed by the database and available at the PDMS are exported automatically. Most of that exported data can be matched and imported automatically to the corresponding records of the database. Invalid or unclear data must be checked with additional information from the PDMS by some validation routines. Some few patient data can only be validated and be attached to the corresponding data record by a medical user working at the unit, because of sometimes unclear or incomplete PDMS documentations. The mentioned problem of unclear documented multiple births may lead to extensive investigations of the mother and children medical records.

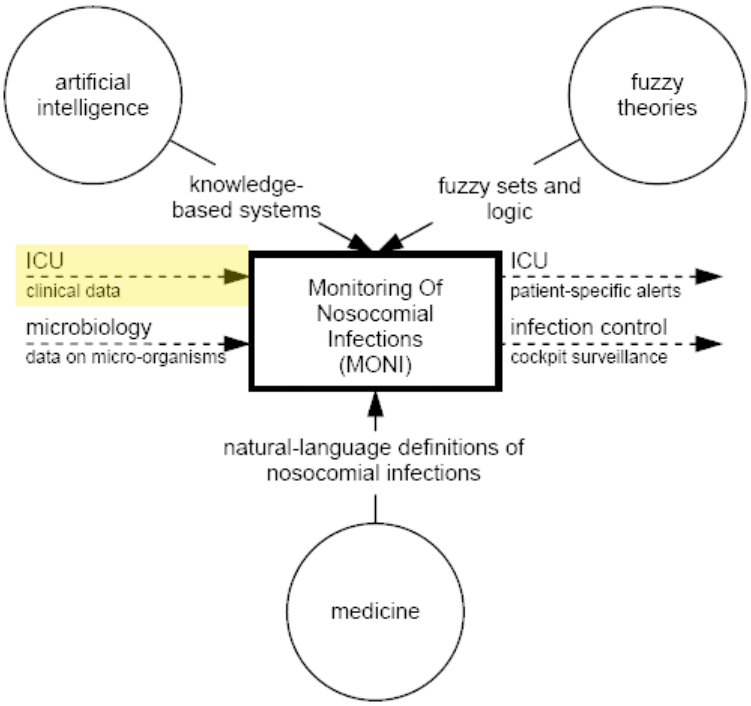
The “scientific database” of the NICU is used to get information about the quality of medical work at the ward. It supports experts and involved users at the NICU to develop rules for medical decisions supporting systems. The database is also helpful extracting information to develop and validate medical guidelines, protocols and ward specific standard operating procedures (SOPs).

6.3.4 Infections monitoring

The project MONI "MONItoring of Germs and Antibiotic Sensitivity Patterns, Crossinfections, and Nosocomial Infections by Applying Knowledge-Based Techniques" is currently adapted to the particular requirements of neonatal intensive care. Together with the department of "Hospital Hygiene" and the department of "Medical Computer Sciences, Section on Medical Expert and Knowledge-Based Systems" of the Medical University of Vienna the knowledgebase and patients' data definitions for the infants' infections identifications are created at the NICU. Because the surveillance of nosocomial infections is a very important task for infections control, all possible data sources need to be addressed by the system. Especially patient-oriented monitoring of suspected nosocomial infections needs clinical patient data additional to the microbiological information of the patient.

Any infection relevant data and information about the patient documented at the PDMS of the NICU is exported to the MONI system. Because the infection alerts of the system need contemporary data the export is executed as soon and often as possible. There are validation processes implemented during data export and import. The data of the microbiological laboratory system are linked to the patient data from the PDMS.

The knowledge-based monitoring system of germs and antibiotic sensitivity patterns and crossinfections analysis the collected data with monitoring rules developed from natural language medical knowledge about nosocomial infections to support the medical decision process. The actual version of the system with methodological framework of fuzzy theories performs successfully and applies in the extended real clinical setting of the NICU. A data flow overview of MONI using the "magic arrow" taken from [Adlassnig K.P., et al., 2005] is shown in [Figure 11].



[Figure 11]: Medical and formal areas that constitute the methodological basis of MONI

A detailed description of the MONI system and can be found at [www.meduniwien.ac.at/msi/mes, 2008]. Interesting articles published about the project are [Adlassnig K.P., et al., 2006] and [Sageder B., et al., 1999].

Another project about neonatal infections the NICU cooperates with is the RALIS neonatal sepsis alert system by Integralis Ltd. Israel. The NICU exports five vital parameters and two documentation fields for specific intervention and medical events from the PDMS for selected patients. The validation of the detected infections is done by a physician at the NICU with additional information manually. This study project is running since 2006.

The NICU joined the NEO-KISS surveillance system for nosocomial infections at neonatal care as well. More information about that infection surveillance system can be found at [www.nrz-hygiene.de/surveillance/neo.htm, 2008].

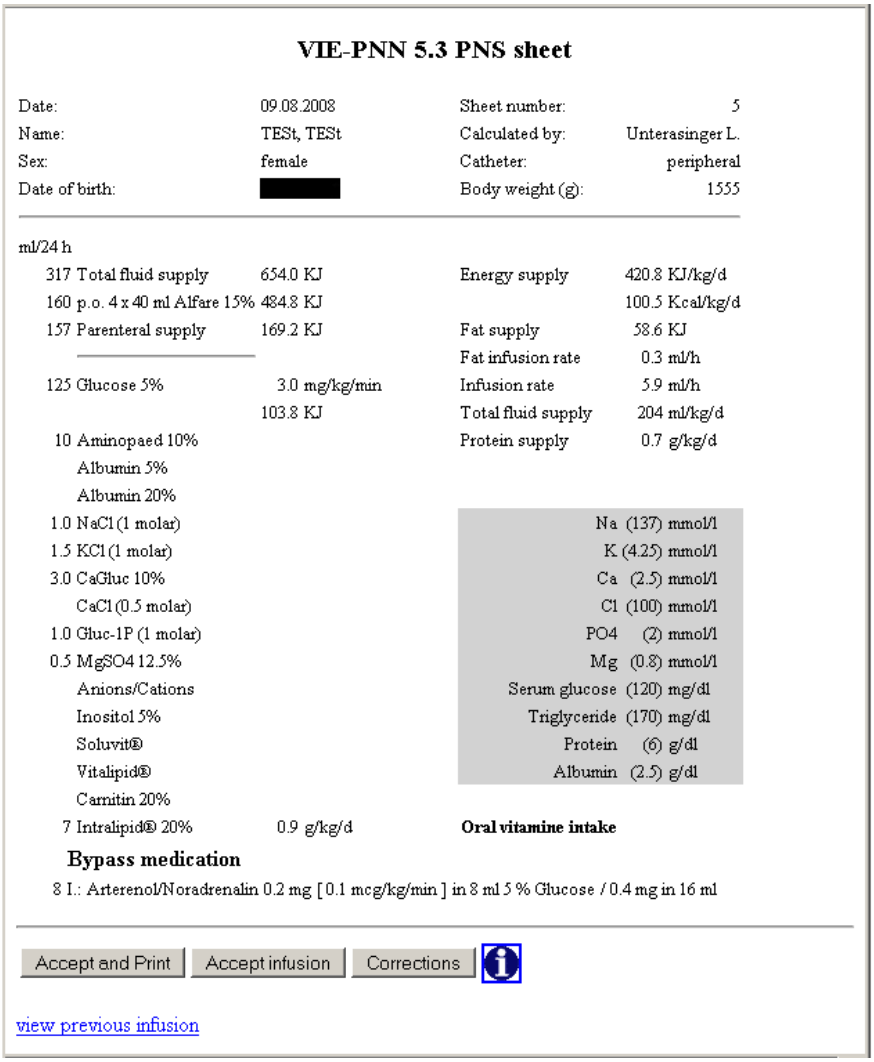
6.3.5 Knowledge-based expert system

The knowledge-based system (KBS) VIE-PNN (Vienna Expert System for Parenteral Nutrition of Neonates) for calculating the parenteral nutrition of newborn infants is routinely used at the NICU since 1996. It was developed at the NICU by Werner Horn, Andreas Seyfang, Silvia Miksch from the Austrian Research Institute for Artificial Intelligence (ÖFAI) and Christian Popow, former chief physician of the NICU.

The system was designed to reduce daily routine work and calculation errors. The task to calculate daily changing compositions of parenteral nutrition for small newborn infants is time consuming and needs experience and expertise.

VIE-PNN is a very robust system using HTML-based client-server architecture with cgi-programs written in PERL. It is used to calculate more than 5000 nutrition sheets per year. The system was evaluated and the results published at [Horn W., et al., 2002 a]. It shows a reduction using VIE-PNN from 7.1 to 2.4 minutes per patient nutrition calculation, which sums up to a daily time saving of more than 1 hour for 16 patients at the NICU. A significant reduction of errors was shown as well. The interactive interface of the system for editing calculation rules, adaption of value ranges and rounding rule enable an easy way for maintenance and keeping the system up to date. The application servicing interface is also used to update nutrition ingredients and appropriate bypass medications and drugs. The explanation facility using an easy information button of the system helps a lot to establish confidence in the conclusions of VIE-PNN.

The excellent and provident concept and realization of the system made it possible to utilize daily routine work at the NICU for more than 10 years now. The [Figure 12] shows a final composition of the parenteral nutrition solution generated by VIE-PNN. The “information” button for explanations is shown at the end of the page. An example of the VIE-PNN maintenance interface is shown in [Figure 13].



VIE-PNN 5.3 PNS sheet

Date:	09.08.2008	Sheet number:	5
Name:	TESt, TESt	Calculated by:	Unterasinger L.
Sex:	female	Catheter:	peripheral
Date of birth:	[redacted]	Body weight (g):	1555

ml/24 h

317	Total fluid supply	654.0 KJ		Energy supply	420.8 KJ/kg/d
160	p.o. 4 x 40 ml Alfare 15%	484.8 KJ			100.5 Kcal/kg/d
157	Parenteral supply	169.2 KJ		Fat supply	58.6 KJ
				Fat infusion rate	0.3 ml/h
125	Glucose 5%	3.0 mg/kg/min		Infusion rate	5.9 ml/h
		103.8 KJ		Total fluid supply	204 ml/kg/d
10	Aminopaed 10%			Protein supply	0.7 g/kg/d
	Albumin 5%				
	Albumin 20%				
1.0	NaCl (1 molar)			Na (137) mmol/l	
1.5	KCl (1 molar)			K (4.25) mmol/l	
3.0	CaGluc 10%			Ca (2.5) mmol/l	
	CaCl (0.5 molar)			Cl (100) mmol/l	
1.0	Gluc-1P (1 molar)			PO4 (2) mmol/l	
0.5	MgSO4 12.5%			Mg (0.8) mmol/l	
	Anions/Cations			Serum glucose (120) mg/dl	
	Inositol 5%			Triglyceride (170) mg/dl	
	Soluvit®			Protein (6) g/dl	
	Vitalipid®			Albumin (2.5) g/dl	
	Carnitin 20%				
7	Intralipid® 20%	0.9 g/kg/d		**Oral vitamine intake**	

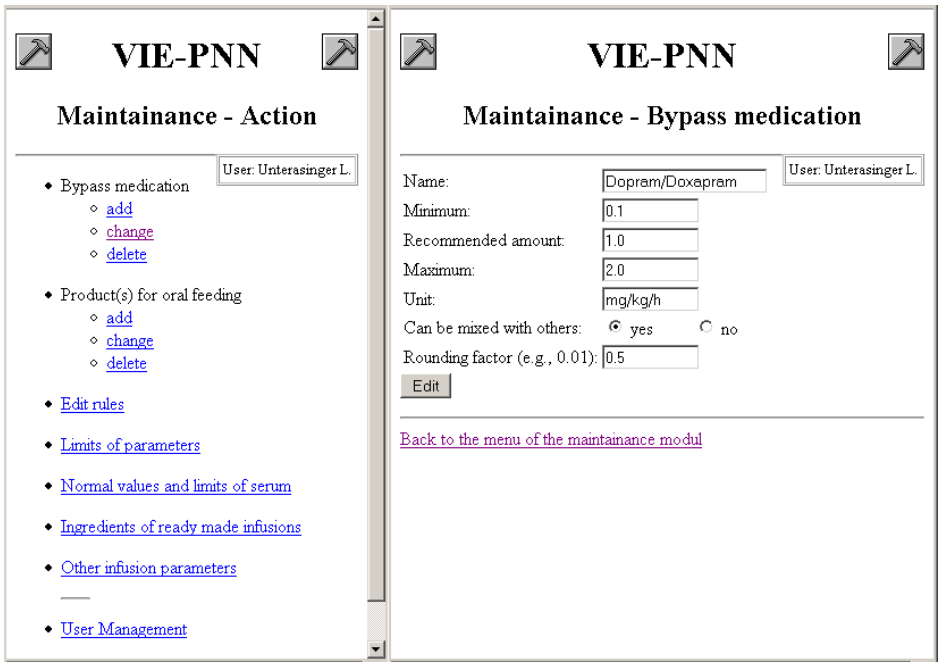
Bypass medication

8 I.: Arterenol/Noradrenalin 0.2 mg [0.1 mcg/kg/min] in 8 ml 5 % Glucose / 0.4 mg in 16 ml

Accept and Print | Accept infusion | Corrections

view previous infusion

[Figure 12]: VIE-PNN html-page showing final composition of the parenteral nutrition solution



[Figure 13]: VIE-PNN maintenance: menu of possible actions; Editor for bypass medication limits and definitions

VIE-PNN runs on a web browser of the PDMS environments and can be used at point of care or other PCs at the NICU connected to the intranet of the PDMS. The goal to integrate the system into the PDMS unfortunately could not be reached because of its restrictions to be a closed patient documentation system not allowing any execution of foreign processes. It is even not possible at the time to get the ten laboratory serum values from PDMS database at the required time. The causing problem is described detailed in section 3.3 problem-description as “time-problem”.

Because there are only few data needed to be entered manually instead of importing them from the PDMS, this disadvantage of additional input was rather easily accepted by the users. The major problem is that the calculated results of the patient nutrition solution (PNS) can not be imported into and viewed by the PDMS. At the moment the printed output of the PNS is kept supplemental in the patient record paper file.

The actual version of Philips PMDS called ICIP, described at [ICIP IntelliVue, 2007], offers methods to integrate such a system. In near future it should be possible to reach the goal of strong integration of VIE-PNN into the PDMS of the NICU. More information about the VIE-PNN Project can be found at [www.ai.meduniwien.ac.at/imkai/kbs/vie-pnn.html, 2008]. Another excellent paper about the evaluation of the VIE-PNN system is [Horn W., et al., 2002 b].

Another knowledge-based system running on the same environment as VIE-PNN at the NICU is the Vienna NeoFax Medical Assistant VIE-Nmed. The aim of the system is the support of drug prescription for sick neonates. It shows information about drugs, their proper prescription and utilizes the users with an intelligent dose calculator. The knowledge was gathered from the NeoFax medication reference book [Young T.E., Mangum O.B., 1994-2008] and information about drugs used at the NICU. The shown information about generic drugs is dose, uses, adverse effects, special considerations/preparation and some others. A subsystem provides information about drug

prescription rules of specific problem areas and diagnoses. A dose calculation after entering the patients´ weight is part of the system. VIE-Nmed does not need any data exchange with the PDMS because it is used as a knowledge-based electronically reference system guiding neonatal professionals to aid the medication treatment of neonates. The system was developed at the NICU by Werner Horn, Silvia Miksch, Christian Popow and others.

6.3.6 Data visualization system

The data visualization system VIE-VISU uses multiples to present the change in the patient's status over time. Because of the vast amount of patient data presented at NICU environments it is often difficult for physicians to recognize essential changes of patient condition over time. These changes in patient's status over time are pictured by 24 multiple frames as highly structured metaphor graphic objects. The time scale of 6 hours to 6 days can be selected by users. Each object visualizes important patient information about body circulation like, BP and HR, respiratory data like pulsoximetry SpO2, and type and parameters of ventilation and fluid balance information.

The main goal of VIE-VISU is fast comprehension and easy analysis of patient's situation chances. The figures taken from [Horn W., et al., 2001] show the 24 metaphor graphics [Figure 14] and single ventilation situations with data legend [Figure 15].

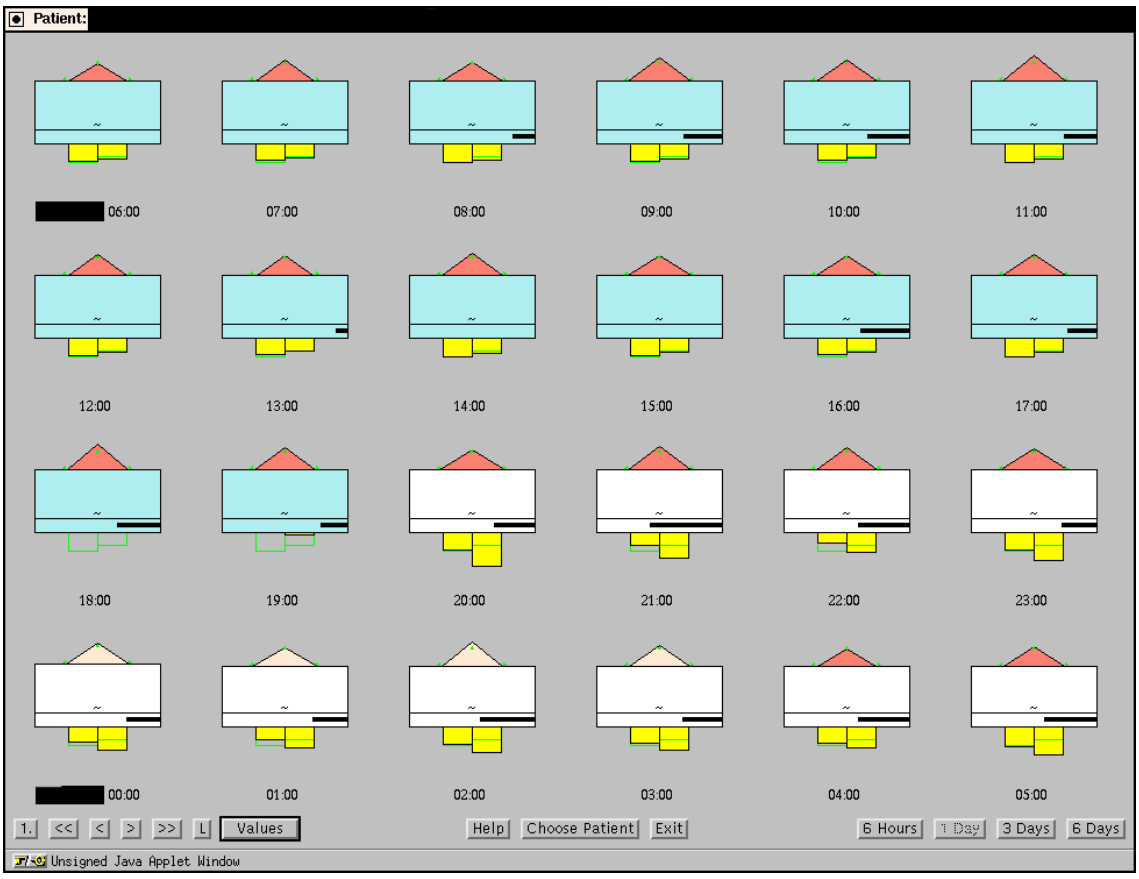
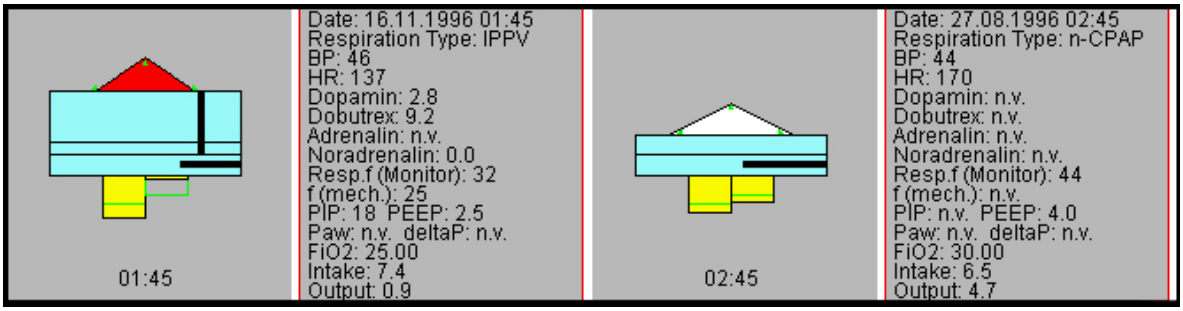


Figure 14]: VIE-VISU: display of 24 hours changes of patient's condition



[Figure 15]: VIE-VISU: highly structured metaphor graphic object for different ventilation situations

This system was implemented by team members Barbara Riepl, Christoph Stocker, and Werner Horn of ÖFAI and Christian Popow at the NICU. VIE-VISU is running on the PDMS environment of the NICU as a client-server application and can be activated at point of care and other connected PCs. The system is a Java based application communicating with a server providing the necessary patient data. These data can be daily exported daily from the PDMS database. The VIE-VISU system would provide vital parameters of higher dense than stored in the PDMS database. The visualization system requires more accurate patient data then available at the PDMS database schemas CDA and ISM.

The associated problem areas of PDMS data export are described in section 3.3 as “density-problem” and “time-problem”. Evaluating the system usability and performance to provide medical work at the NICU with a clinical study is outstanding and should be done in near future. More information about the VIE-VISU system and publication on the subject like [Horn W., et al., 1998] can be found at [www.ai.meduniwien.ac.at/imkai/kbs/vie-visu.html, 2008].

6.3.7 Ventilation support system

Some years ago the VIE-Vent Project was executed at the NICU by the already introduced team of Werner Horn, Silvia Miksch and Christian Popow together with Franz Parky. The aim of this project was developing a knowledge-based monitoring and therapy planning system for artificially ventilated newborn infants. The system should support neonatologists in their daily routine.

VIE-Vent is an open-loop, real-time constrained system for optimizing mechanical ventilation of neonates. As data input for the system, quantitative on-line values like ventilator settings and blood gas measurements and qualitative off-line clinical parameters is used. The outputs of the system are warnings, explanations, comments and recommended ventilation setting for therapy planning. Most of the real-time data are received from on-line monitoring and ventilation machines. The main effort of the system is data validation to detect, eliminate and repair faulty data automatically. Combined knowledge-based methods applied to continuously-assessed high-frequency data and discontinuously-assessed data. The system can get only very few information from the PDMS database. It requires direct access to the patient monitoring and other machine interfaces as data sources from the online network via MedCom-Server and MLink-interface.

These system requirements cause special data export routines and interface handling, unlike PDMS data export, to utilize the VIE-Vent system. More project information is available at [www.ai.meduniwien.ac.at/imkai/kbs/vie-vent.html, 2008]. Published papers about the project with complete system description are [Miksch S., et al., 1996] and [Horn W., et al., 1997].

A more recent project about close-loop oxygen control, the NICU is slightly involved with, is published at [Urschitz M., et al., 2004].It compares periods with automatic and routine manual oxygen control with periods of optimal control fully dedicated. The FiO2 controller used at the project significantly increased the proportion of time oxygen saturation levels were within a desired range. But there are further studies needed to test if the close-loop FiO2 controller will not only reduce workload, but can also help to reduce morbidity resulting from unnecessarily high exposure to oxygen or large fluctuations in oxygen levels.

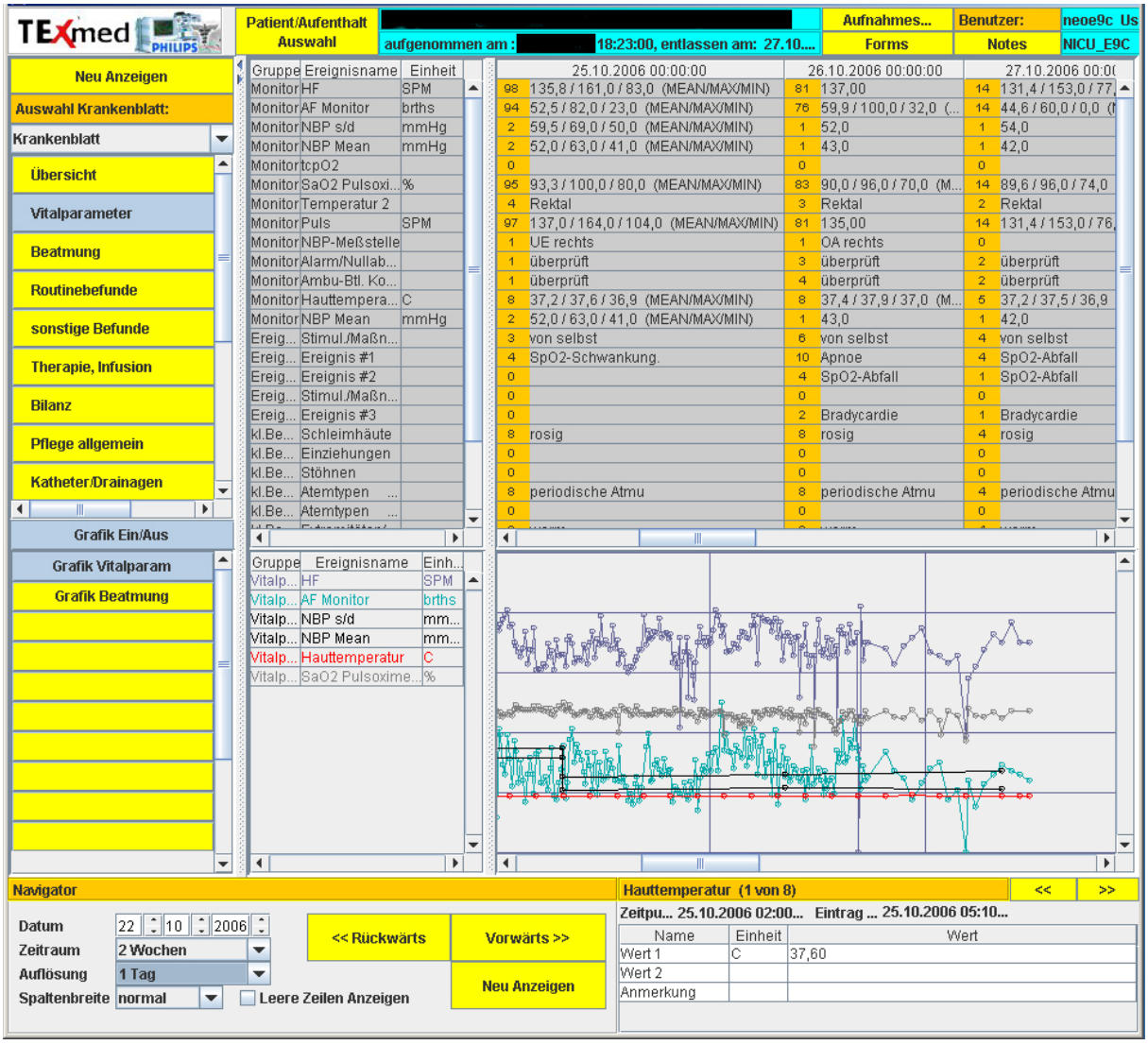
6.3.8 Patient admission reviews

A Microsoft Access application to generate a report at discharge of neonatal patients can be used at the NICU. The application runs on PCs connected to the PDMS intranet with access to the PDMS database schema ISM (Information Support Mart) via ODBC. A translation of the application to a dynamic web-based version is projected to run with intranet web browsers of the PDMS equipment. The system uses daily exported specific patient data and information.

The generated reports of the patients at discharge sum the desired information about the complete admissions. These are summaries of ventilation therapy days, applied medications, important laboratory results, special events at treatment and the nutrition of the patient at discharge. The application maintenance to keep it up to date is done at the NICU by editing the export scripts and the MS Access layout.

The commercial Java application “ISMartVue” of TEXmed GmbH and Philips Healthcare to show the complete documentation of patient’s admission stored in the PDMS ISM database schema is installed and used at specific PCs at the three neonatal units. The system is qualified to retrieve any data and information documented with the PDMS of the units in a similar presentation. So medical users practiced on the PDMS can easily find specific information about patients who were discharged from the units up to 5 years ago.

The system supports no data validation or valuation and summaries of facts of the patient documentation, but any value entered to the PDMS can be discovered. It is possible to display numeric values of specific vital parameters in time-oriented charts like the PDMS. To display a good overview about several weeks of the patient’s admission the solution of a data row can be chosen from 15 minutes up to one week. The number of values of a parameter is shown and the single content and timestamp can be displayed in a separated part of the application. Numeric values are presented as minimum, maximum and mean of the selected time period. “ISMartVue” is a supporting tool to find explicit information about a patient and utilize the validation of complex analysis processes for evaluation of patient’s treatment quality. The [Figure 16] shows an information display example of the application.



[Figure 16]: ISMartVue – display of specific spreadsheet data of 3 admission days (in German)

6.3.9 Ward specific CPGs, protocols and SOPs

Developing standard operating procedures (SOPs) and protocols for patient treatment of selected medical problem areas is an important mission at the time. The validation of such protocols and SOPs at the NICU can be done with some named QM systems. The cognition and execution of evidence-bases clinical practice guidelines (CPG) published by national and international healthcare organizations and societies is an ongoing urgent process affecting the NICU and other parts in medical treatment of newborn infants. Some overview information about guideline developing can be found in [Shekelle P.G., et al., 1999].

The highly recommended Cochrane Neonatal Review Group (CNRG) [www.neonatal.cochrane.org, 2008] produces and disseminates evidence-based, regularly updated reviews of the effects of therapies in neonatal-perinatal medicine. The CNRG is funded by the national institute of child health and human development (USA) which maintains also an internet

archive: [www.nichd.nih.gov/Cochrane, 2008]. These internet archives of neonatal reviews can help improving the quality and safety of medical care of newborn infants, when used to develop and validate ward specific SOPs and treatment protocols.

A considerable job of quality management and quality improvement at the NICU for the next time will be the development and computerization of such ward specific protocols. Different guideline modeling formalism exists to utilize the definition procedure and get computer-interpretable structures as published in [Peleg M., et al., 2003].

Excellent tools like “Asgaard” and the system “Asbru” for guideline representation help to perform such complicate abstraction and time line visualization tasks. Publications about the project are [Miksch S., 1999] and [Aigner W., Miksch S., 2006]. Complete information about the system can be found at [www.asgaard.tuwien.ac.at, 2008]. Other remarkable projects and tools associated with the problem of integrating computerized protocols and clinical practice guidelines to medical routine work are shown at [ieg.ifs.tuwien.ac.at/projects, 2008].

Many alternative concepts and potential methods are feasible to integrate ward specific SOPs and protocols into the clinical routine of the NICU. The potential of using free and open source technologies for such patient-centric, guideline-based clinical decision support is described in [Leong T.-Y., et al., 2007].

The implementation and execution of such computerized time relevant ward specific protocols and SOPs on the PDMS environment accessing its patient data and information will be an exigent and challenging interdisciplinary team task for the NICU. The developing process and the realization will help a lot in workflow management at the NICU.

6.3.10 Other QMS applications

The patient data from the PDMS database and the support of the abovementioned QMS with their additional medical information are used for several clinical studies and research projects at the NICU.

Some other IT-systems not explicitly named here were used and developed for QM at the NICU. Some more, and maybe completely different, QMS will obviously be implemented at the NICU and its rich IT environments. All systems used for quality management have the essential intention to communicate with the central PDMS documentation system. Data exchanged between the systems and an explicit patient data and information export from PDMS databases is mandatory for most of the QMS. Developing a clear defined and shareable data exchange concept for the NICU is essential for using and integration such QMS on the given IT equipments. Solutions for some problems and a concept for such defined data export from the PDMS database is presented in the next section.

7 Solutions: Connecting QMS to PDMS-data

The often similar requirements of a defined export of specific patient data and information from the PDMS database for different QM-systems resulted in the development of a balanced and proved concept for such tasks. Additional to the applications at the NICU, using exported data from the PDMS, some more systems at other units and hospitals caused the elaboration of that export concept.

The periodical export of ICU data for the defined dataset of NICE, described in [Arts D.G., et al., 2002 a], was one of the first performed solution with such a construct. That took place in 1999 at the AMZ Maastricht, NL. At the same time ASDI defined the intensive care minimal data set. It was the template of the patient data records collected by the Austrian Ministry of Health for cost accounting from every ICU in Austria. The export of that well defined so called “BMAGS” dataset from the PDMS database was a project at the Vienna General Hospital. Both export intention were well support and exactly designed. The data export was scheduled periodical but not time relevant. Most of the described problems of exporting information and data from existing PDMS databases could be solved with that solution design.

More export projects, like QMS abovementioned, were successful realized the following years. The design of the export process slightly chanced and was optimized over the years. Some of the developed export procedures needed more accurate patient data. The export routine needed to start sometimes on demand and sometimes scheduled. Some of these completed projects, implemented with the illustrated PDMS data export solution concept, are running until now. Detailed descriptions about those projects will be presented at the evaluation-section.

The specifications of the used PDMS at the intensive care units with accessible documented patient data and the requirements of the QMS connected to that data and information are illustrated in detail at the above sections. The implementation of the connection between those systems to retrieve already stored information about the patients is a process that will last over a long time. Both IT systems, PDMS and applications used for QM, are modifiable and must fit the changing needs of medical treatment documentation and evaluation processes.

The concept of that systems connection for PDMS data export must comply with changing environments and demands. Already at initial concept implementation of the data exporting routines an evolution loop, to keep the subsystems actual, should be established. The integration of processes for regular evaluation of completeness and quality of data for the systems is essential for the prosperity over long time. The presented solution and concept in this section are used for well established systems of information retrieval from PDMS for QMS at the NICU and other intensive care units.

7.1 Concept of PDMS-data export to defined QMS

All tasks and specifications required to develop such data export system are pointed out at this section. Some development steps can be performed simultaneously, others are depending on each

other. The presented solution concept consists of the completion of the required development and specification tasks specified.

7.1.1 Compliance of premises and recommendations for the QMS

All technical and software requirements for the QMS, connected to the PDMS database source, listed in [Table 12] at section 6.1 must be met by the used HIT system. The system used for QM must provide functionalities to access the needed data exported from the PDMS-DB. The necessary interfacing, performance and software requirement for user interaction must be checked as soon as possible, even before starting to implement the export process for the system.

7.1.2 Definitions of the data export

According to [Table 12] “QMS premises and recommendations” at section 6.1, all required definitions and recommendations must be achieved. It can be time consuming to get all required information about the QMS. Therefore it is often reasonable to involve expert physicians, trained nurses and persons with some experience with that complex definition processes. Without complete and valid definitions of the data required for the QMS and clear defined export criteria the development of the export process can impossible succeed. So it may be expedient to invest time designing and improving the QMS before starting to export patient data from the PDMS database. Without the required definitions the exporting system will only deliver some unclear data about some patients which can not be used as data source for any serious system to improve the quality of patient care. Most of the listed recommendation in [Table 12] should be performed to support implementation and help maintaining the system.

The definitions about data and the export process description should be documented and stored in tables to be used as specifications for the needed data export system. Any later changes of the QMS should start updating that specification documents. It must be verified if the necessary adaptations can be done without a complete redesign of the export routine. For maintaining the system clear and complete documentation of required definitions will be fundamental.

- Definition of conditions and restrictions for the export
- Definition exclusion and inclusion criteria for patient admissions
- Definitions for every parameter of required patient data and information

7.1.3 Design of solution tables (specific data mart for QMS)

When all definitions are done and documented it is requisite to design the tables to hold the exported data for the QMS. Relations between the defined result tables must be shown. The relational database concept used to store all needed patient parameters and information about the export itself can be called “data mart” for the QMS presenting the required patient data.

The database design should contain a table for essential patient admission information and an additional table for facultative information about the patient. A table with patients discharge

information and a table to hold all required and potential patient identification numbers should be defined. It can be reasonable to create individual tables for all kinds of data types or for logical connected information. It should be concern that some data may be exported rarely during patient admissions and others daily or more frequently. The defined data types and ranges and the given data formats of the source PDMS database should be respected by the design of the data mart tables.

Specific tables to communicate with the QMS are essential to produce prospects to generate messages for the systems about occurred errors, problems or data validations at the export process.

It is advising to design tables holding information about the export-parameters, similar to the documented definitions and linked to the used sources values. These tables will allows the QMS displaying information about the parameters including their restrictions, applied calculations and data ranges together with information about the source values used to generate the parameters to system users.

An explicit table to store the control parameter of the export and the requirements of the export process should be designed and be accessible for the QMS.

The necessity to design and create such data mart with tables to store the needed patient data and information from the DBMS database for the QMS exists, because direct data access to the DBMS-DB is normally to slow and sometimes impossible. Reasons for that problem are possible security and prioritization specifications, the complex database structure and often enormous data volume of the PDMS-DB. In spite of high performance hardware, software and interfacing accessing specific nested data from the complex DBMS-DB structure may take several minutes up to some hours. <Problem of performance and security>

The use of such special designed data mart to hold the needed data for the QMS allow scheduled data acquisition at defined time and priority for exporting processes. Security demands can be met easier with clear defined conditions. The prepared data for the QMS by the scheduled export process will not be accurate but available after defined time borders. Direct access to the PDMS data source can not be accurate as well, because of before mentioned problems.

The time period the data mart is storing the data must be defined. Several techniques can be used to keep the volume and timeframe constant at the tables of the data mart.

The solution, using such explicit data structure with specified tables, for the needed export parameters will be profitable, if other data sources must be accessed additional to the PDMS-DB. The QMS can use a single source for data import, not attending which different systems are used as data sources by the data export process.

The goal of the data mart design is an optimized and easy interpretable structure for the QMS. For the QMS every needed parameter with information about the source data and applied processing can be accessed directly, without additional interfaces to other IT-system data.

The design of data mart and the applied DB-concept should allow high flexibility to provide further demands of the export system.

7.1.4 Mapping table of parameters needed by the QMS with PDMS DB source

According to the parameter definitions for the QMS and the tables of the export data mart, holding these definitions, the PDMS must be scanned to fetch the corresponding patient data. For each defined parameter of the QMS, all possible documentation rows and fields in the PDMS with the related information must be found and mapped as source data. If someone is not very familiar with the PDMS and their using practice, this can be a demanding and nearly impossible task.

It will be very helpful to ask trained nurses and physicians at the unit where in the PDMS they document or find needed information about the patient. Additional the database of the PDMS should be scanned to find configured data rows and fields about the wanted information. Searching specific input values will produce hints where in the PDMS database the needed information can be found. This additional searching in the PDMS database is required because even experienced users do not know all possibilities documenting patient data, especially if used very rare. But if the specific information is documented with the PDMS it can be receivable with the export process to the QMS.

To find the tables, rows, and all necessary joins between the tables, to access the data for the export can be difficult because of the complex structure of such PDMS databases. To know all required links and a have a complete knowledge about the database with their about 300 nested tables will take some time. It can be very helpful to use a “test-patient” to document complete data dummies at all needed input-fields and find the places and links in the database by searching the documented dummy-values. Such “test-patient” will be very supporting when testing calculations and translations used by the export process. There are some more options to deal with the <Structure – Problem> characterized at section 3.3.

It might be required to update and complete the definitions of the required parameter with rules to use the data sources. <Problem of differences between documented data and required information for QMS>

The resulting table with definitions for all parameters for the QMS and the mappings to their data source in the PDMS database can be a complex map defining many calculation and assignment rules. Imagine that the wanted information about the patient ventilation is of four possible selections but the source data about the ventilation may be documented in several different places and must be combined to generate the correct result for the parameter. For some scoring systems it might be necessary to calculate a parameter like “arterial oxygen partial pressure” from several source data fields as the value which is together with the “inspiratory oxygen concentration”, from several source data fields as well, as an index a minimum over 24 hours. In case of doubt calculate the minimum measured “arterial oxygen partial pressure”. Such rules for calculations and mappings can lead to rather complex and complicate definitions in that parameter table for the QMS export.

If parameters needed for the QMS are not documented or can not be found with defined requirements in the PDMS, a solution must be found as described in section 6.2. It may be demanded to reconfigure the PDMS or access other data sources. To implement the data export it is essential for each required parameter with their conditions and restrictions to define the export process from the

data source. It may be defined that for a specific parameter nothing is exported. The values for that parameter will be entered to the QMS by users if needed.

This data definition table for the export process is the foundation to lead the data processing and keep the system maintainable and flexible for the future. It will be the base and core of the entire system to bring information of the standard documentation with the PDMS to the system used for quality management.

7.1.5 Control table for export processing

The definition and creation of a table to control and document the export process will help to perform the data export for the QMS. Previously defined conditions and restrictions for the export with exclusion and inclusion criteria for patient admissions are presented in that table. By editing the table the export system can be configured. Definitions like a minimal admission time required at a unit can be changed. This can be done by editing the table with any interface or the QMS with access to the table.

The table includes fields to set an export start date and an export end date to start the export for a so specified time interval. The date of the last exported parameters and the time when the export was executed are stored in that table. It can be used for communication between the user of the QMS and the export process.

A well designed export control table will keep the export system flexible and maintainable. With such tables the export routine to the data mart can be used scheduled or on demand (time or event triggered).

7.1.6 Design Export-Routine and Environment

The definition of additional tables for processing the export and communication to the QMS will complete the data mart for the PDMS data export. The use of temporary data tables and specific calculation tables may be required. Specific tables to store error messages and other information of the export process which should be accessible from the QMS can handle some needful and useful communication between the involved systems. Defining a table to store information and comments from the QMS used by the export process can support the solution as well. Tables used to generate valid patient census under required condition are also necessary. Some changes of these additional tables will be performed during the implementation of the export.

A concept for data correction and system behavior during re-export of data must be found. Considering the specifications for the export, the system must handle the problem of a time delay because of the possibility to correct or add data to the PDMS 24 hours later specified as <Correction – Problem> and <Time – Problem> earlier. The solution concept will enable overlapping data export of a specified time interval, to update and correct already exported data. This concept must be provided by the application of the QMS.

The scheduling process and additional possibilities to execute the export process must be defined. Already existing system environments like Oracle™ grid-control or scheduler of the operating system should be used. It should be kept in mind developing some communication routines between the involved systems.

Additional administration tools to establish some “watchdog” functions to alarm systems, administrators or users should be defined. These tools can be used to handle backups, system recovering and other administration task for the export process.

Additional interfaces to start the export on demand and editing the control table of the export for the QMS should be defined. An easy web-interface may be used to configure and administrate the export process using the control table. Any effective procedure for such tasks must be defined.

A procedure to keep the volume of the data tables of the data mart constant must be defined for the export process. According to the specifications, this procedure must clean the data of the export system by deleting or copying them to other tables. Special tables can be used for this process to mark patient data to be not longer used by the QMS. Specific rules for this process, like “delete any patient data when discharge of the patient is more the 10 days ago”, can be defined. Any kind of cleaning procedures must be defined and established at the export system.

Additional communication procedures between involved systems, administrators and users should be defined as well. This can be done using easy LOG-files of the export process or establishing complex data communication streams. The communication processes will help to maintain the system and allocate failures of the involved systems. Especially when testing the export of the patient data from the PDMS to the QMS such procedures will be very valuable.

7.1.7 Developing the “Data Mart” and tables

The tables of the Data Mart must be implemented with technical environments where the DBMS-DB is accessible and which can be assessed by the application of the QMS. Commercial database systems like Oracle™ and Microsoft™ SQL-Server are the best choice for a stable and professional system for the data mart. The open source product MY-SQL could to be used, but that will generate some more work for administration and questions about system integration and juridical aspects. Small database application systems like Microsoft™ Access, Informix Dynamic or Filemaker™ can theoretically be used, but are not recommended because of system stability, performance and the miss of adequate administration tools.

The best decision is to use the DB-System of the PDMS database because accessing the source tables is fast and direct, and the DB-Administration tools already installed can be used. The user management for the system can be integrated to the existing concept of the PDSM database.

The schema, table spaces and users with granted properties must be created on the DB-system. All required database links or views must be created to access the source tables of the PDMS database. The defined data tables, definitions tables, control tables, communication and error tables and the tables used for temporary calculations and storage must be created. The indexes and constrains of

the tables must be set as well. According to the expected data volume of the tables the according data files must be defined and created. All required administration processes for the data mart with the deployed DB-System should be used and tested soon in the developing process.

The creation of the data mart including all processes for table spaces, indexes, constrains, users, schemas, tables should be implemented with executable scripts for easy installation and move to different system environments. A fast end easy reinstallation can be executed with those scripts. The initial filling of the parameter definition table and the control table for the export processing can be done with editable executable scripts or the defined administration interface for the system. Any changing in those tables must be stored for further recreation of the system.

7.1.8 Developing the export program and queries

The code and queries for the export process itself must be written. Any programming language can be used which is able to perform queries for writing and accessing the data mart. The use of JAVA™ or any ".NET" language to write executable programs is possible like writing any web-based system running with CGI-executables.

For the introduced PDMS data export projects the export procedures are implemented using the Oracle™ Programming Language PL/SQL of the PDMS database system. This language can be use to write procedures and functions which can be executed by the Oracle™ system and can perform direct SQL statement executions by the database server. The system includes tools to optimize SQL-queries and measure the performance of the developed export procedures.

It is a good concept to structure the required export processes by developing subprograms and independent functions and procedures. Some parallel executed processes can speed up the export process but mutual locking of tables at writing must be avoided. Some skills in programming such processes are essential to implement a stable, effective, fast and maintainable exporting system.

The written code and the developed procedures should be easy readable and well commented like at any software development project. The code and programs must be easy adaptable to use them for several DBMS data export projects for other QMSs.

7.1.9 Implementing the system interfaces

The defined environment for system interconnections and security must be implemented. This task includes Log-file handling, user management, specific systems communication processes and the integration of required tools and applications for system administration. The implementation of the defined scheduling system is part of this task.

This workload for the implementation can differ a lot constrained by the options of the IT environment of the used systems and the people administrating them. The success of such project can be up to the quality of the engaged systems and the involved IT-staff.

7.1.10 System documentation

Like any software project, all parts of the export process must be documented well. The documentation will be primarily used to maintain the system. It must be pointed out in the documentation what has to be done if the requirements of the QMS will be changed.

Especially the frequent changes of medical treatment and the documentation with the PDMS must be highlighted in the documentation. Clear instructions should be written, pointing out required tasks for system adaptations, when any changes are done at the PDMS configuration. It is a good concept to implement the documentation with online web-pages addressable from the PDMS PCs and the QMS application.

7.1.11 System testing

Extensive test for all parts and the interactions between the parts of the PDMS data export system shall be done. The test should measure performance, data integrity and validate all parameters exported to the QMS according to definitions and rules.

All tasks for administration like backup, clearing the data mart and the scheduling process must be tested. The proper use of the system communication process must be checked as well.

The testing procedure will take some time and may lead to some adaptations or replacement of parts of the system.

The important and extensive validation if every possible item documented with the PMDS will create the needed parameter to the QMS respecting the defined rules, mappings and calculations, can be done using “test-patients” to generate complete data dummies. It is essential to use the PDMS for that test. They must be done by someone with experience and authorization to use the PDMS at the unit.

7.1.12 Establish feedback circles

To keep the exporting system effective supporting the QMS with PDMS data, some feedback circle between the users of the QMS application and the staff at the unit using the PDMS for patient documentation must be established.

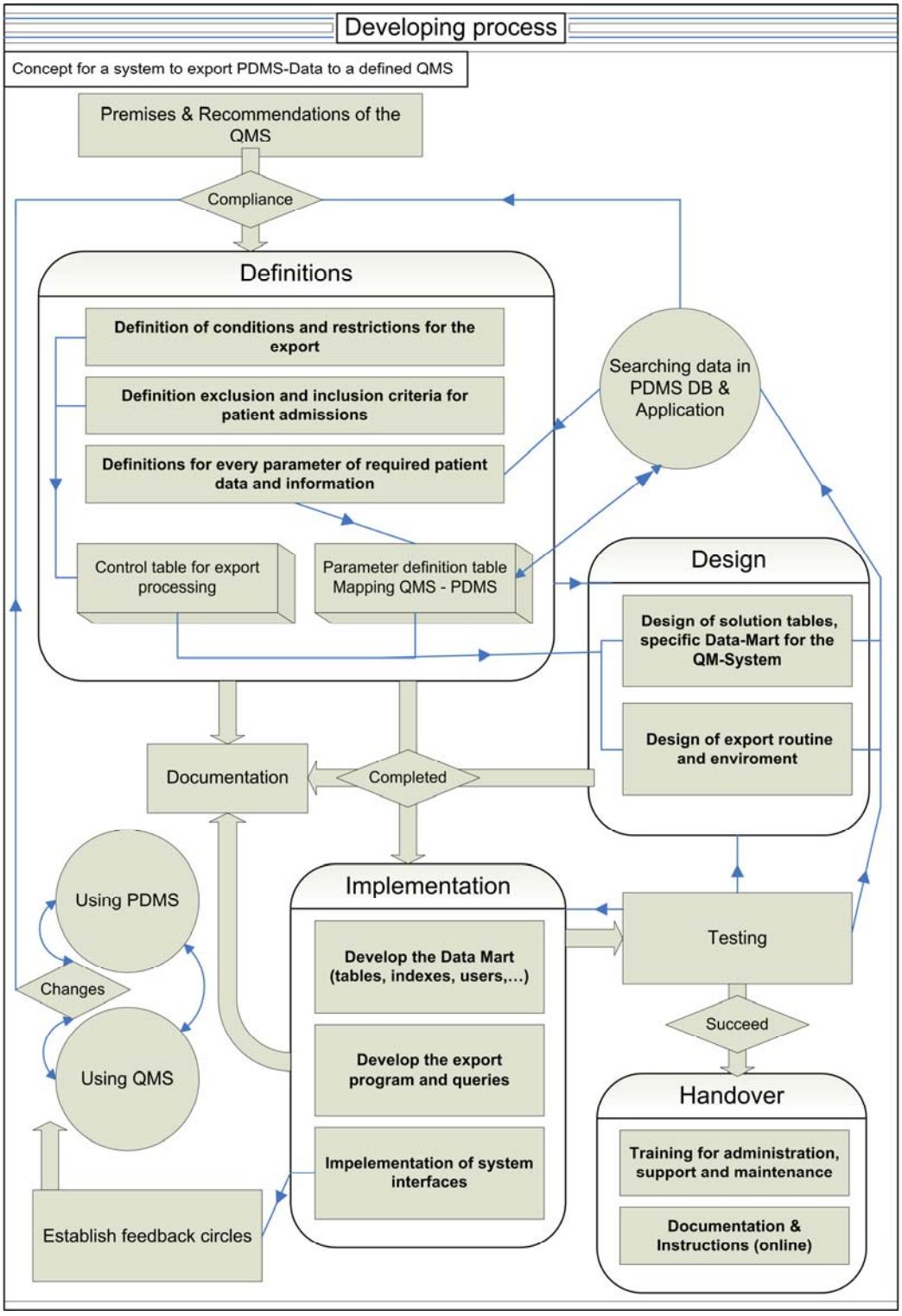
The users of the PDMS at the NICU should be aware that their documentations are used for an additional QMS. The benefit for the NICU staff by sending evaluations of the applied medical treatments, done with the QMS, can be motivating to enter adequate patient documentation. If the QMS supports the nurses and physicians at the NICU directly the motivation will be high, but the knowledge about the system connectivity should frequently be updated.

Changes of patient documentation should be recognized by the QMS users. Extensions of the QMS should be reported to the NICU as soon as possible.

An explicit periodical communication process can install such feedback circles between the QMS and the PDMS.

7.1.13 System development overview

[Figure 17] shows an overview of the developing process of the solution concept for a system to export PDMS-data to a defined QMS.



[Figure 17]: PDMS data export to QMS solution – developing process

7.2 PDMS data export program description

The complete application to export PDMS data for QMS contains following functions and tasks:

- Generate the patient-census:
  As first step of the export process, a valid patient census with all admissions for the export must be generated and written in a temporary table which will be used for the data export. The settings from the export control table are used for each unit of the system separately. If continuous export is adjusted any changes at patient admissions must be activated for the export (new admissions, discharges and readmissions). For on demand export, the admissions between the adjusted time borders defined in the control table must be generated for the data export. All defined rules about admission handling are considered generating the census for the admissions (minimal admission time, merging admission if patient readmitted within defined time interval, etc.). The function considers the configured time overlapping because of possible corrections and additional documentation. Messages and occurring errors are written to LOG-files and messages/error tables for the connected systems.
  ⇒ Function reads: PDMS-DB-tables, export-control-tables;
  ⇒ Function writes: messages/error tables, LOG-files;
  ⇒ Function result: census/admissions in temporary patient-census-table;

- Export patient admission/discharge data and information:
  The generated patient-census with the information about the admissions for data export is required for this function. The function can run before, after or parallel to the patient-data export task, described next. Settings about the export restrictions are received from the export control table.

  All patient parameters appearing once for a single patient admission are exported with this function. The accessed data from patient administration catalogue and forms can be changed at the PDMS until the patient is discharged. These configured parameters are written or updated to the admission and discharge information tables. The configured overlap time is respected exporting the data as well.

  The resulting tables with information about patient admissions, identifications and discharges are source for the QMS. The data are added or updated by the exporting task. It is essential for QMS to detect changes in those tables. A descending numeric counter and the timestamp of the export are generated and exported by the function to identify new or updated information.

  Calculations used to generated admission or discharge parameter are applied from the parameter definitions table. It may be necessary to use temporary data tables for the defined calculations and selection rules.

  Any occurring errors or generated messages for the involved systems are written to the LOG-file and messages/error tables.
  ⇒ Function reads: PDMS-DB-tables, patient-census-table, export-control-tables, parameter-definitions-table;
  ⇒ Function writes: messages/error tables, LOG-files;

⇒ Function uses: temporary data-tables;
⇒ Function result: patient-identification-table, patient-admission-data-table, patient-discharge-data-table;

- Export patient data and Information required by the QMS:
  The generated patient-census with the information about the admissions for data export is required for this export function. The function can run independent from the patient-admission/discharge export task. Settings about the export restrictions are received from the export control table.

  All defined parameters for the QMS configured and stored at the parameter-definition-table are exported with this function. Corresponding to the data tables of the designed data mart for the export, the function generates daily records or other required structures and formats for the defined parameters. Temporary data tables are used for such calculations. This function is the most complex part of the data export process. Dependent on the needed source data from the PDMS DB the data export process at this function can be time-consuming. Optimizing queries and statements, the use of indexes and data buffers together with the required temporary tables is essential within this task.

  The exported patient parameter for the QMS can be newly written or updated by the function, according to configured overlap time. A descending numeric export counter and the timestamp of the export are added to each parameter record to provide the QMS to identify new or updated information. The resulting data tables holding the needed parameters are source for the QMS.

  Any occurring errors or generated messages for the involved systems are written to the LOG-file and messages/error tables.

  ⇒ Function reads: PDMS-DB-tables, patient-census-table, export-control-tables, parameter-definitions-table;
  ⇒ Function writes: messages/error tables, LOG-files;
  ⇒ Function uses: temporary data-tables;
  ⇒ Function result: patient-data-tables defined at the data mart;

- Cleanup data of the data mart for the QMS:
  The function can run independent from other export functions. Mutual locks of writing and deleting processes to the data tables must be avoided. The defined and configured rules for the cleanup procedure are used for this process. If a communication table, to identify data to be cleaned, is used, the function reacts only on that information.

  A defined rule like “Delete/Move all data of a patient admission if the discharge is more than time X ago” is typically for the cleanup procedure. Patient admissions discharged more than time X before export starting time must be identified and, together with all corresponding parameter of these admissions in the patient data table, be deleted or moved to any archive tables.

  This function uses just the data-tables and the control-table of the data mart for the QMS. The data move to archive tables will allow recovering patient admissions parameter and

information. Those archives of the data mart can be used by the QMS to access not only actual or newly exported data.

Any occurring errors or generated messages for the systems are written to the LOG-file and messages/error tables.

⇒ Function reads: data-tables of the data mart, export-control-tables, cleaning-information-table;

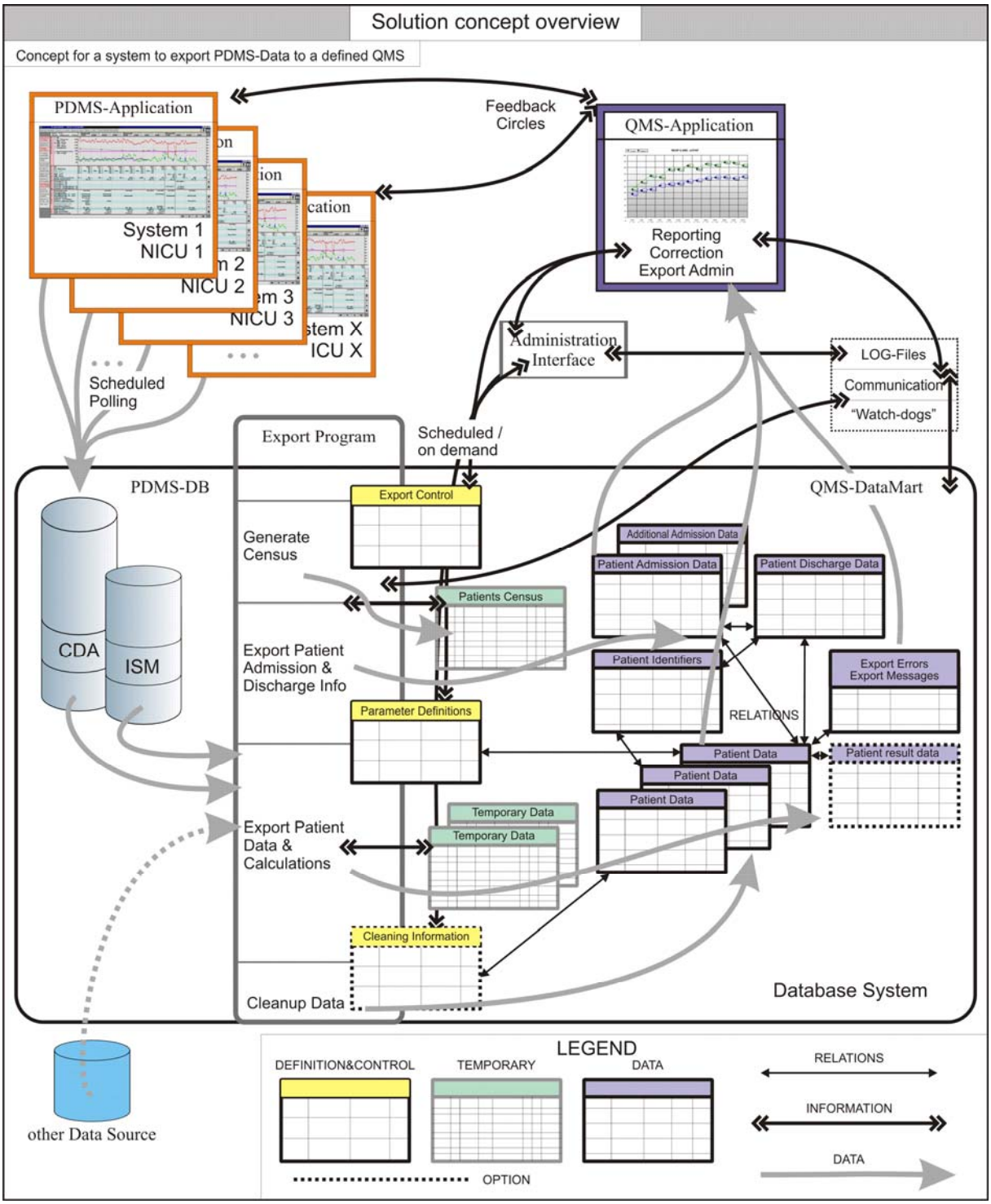
⇒ Function writes: messages/error tables, LOG-files;

⇒ Function uses: data-tables of the data mart;

⇒ Function result: delete/move patient data of the data mart;

Initialization procedures to generate the Data Mart and the required environment are designed as separated function. This includes the control table handling and the parameter definition checks. This function is only used for administration and system maintenance. The execution of this function is handled from administration interface strictly apart from the functions for the export process.

The solution concept overview of the PDMS-data export to a defined QMS application with the described export program is shown in [Figure 18].



[Figure 18]: PDMS data export to QMS solution concept – program execution process

7.3 Solutions of some specific problems of PDMS-data-export

Specific problems about PDMS data export process are characterized at section 3.3. Solutions for that described difficulties with the introduced concept are presented at this section. The arrangement of specified problem solutions shall call attention to expected troubles at implementation of such QMS integration with PDMS data export.

7.3.1 Problem: changing of the documentation process over time

No matter if information for QMS are achieved from pre aggregate using specific data mart or accessed directly from the PDMS database, any changes of documentation behavior at the PDMS must be considered.

Some PDMS configuration changes can be received using parameter of configuration tables in the PDMS database. If drugs, configured in the PDMS, are labeled as antibiotics the exporting process can identify antibiotic medication with newly added drugs for instance.

But there are only few options using information about the PDMS configuration in the database for the exporting process responding to such changing documentation. Normally new parameters are added to the PDMS and used for documentation and others will just stay empty.

So it will be the best solution to use easy configurable definition tables mapping needed export parameters to source data of the PDMS database. These tables should include information about data type, data dimension, range definitions, priority information for source values, statistical information and needed translations and calculations for every parameter as described in the prior sections.

If anything changes at the documentation process with the PDMS the utilizing parameter definition table must be adapted to keep the export process working well. An easy tool for this task will help adapting the exporting system straightforward. Well established feedback circles between the users of the QMS and the PDMS will help to recognize such changing and the adaptation of the export procedure can be covered fast.

7.3.2 Problem: missing or wrong data in the PDMS documentation

There exists the problem of incomplete and sometimes wrong patient documentation during medical work at intensive care units, because of too less time for documentation and the definition of just very few mandatory fields.

Some processes to reduce the problem can be implemented within the export procedures. Routines for crosschecking several source data fields allow identifying wrong documentations. If strong and valid rules are defined, some procedures for automated correction or completion of documentation can be implemented. This will be a formidable task and may cause some even more hidden documentation failures. They may be interpreted as export errors, because the wrong documentation is not seen clear any more. To keep the export system up to date will get more

complex using such data correction procedures. The system should use such procedures rare and wise.

To handle incomplete patient documentation it can be helpful to define default values for the parameters needed by the QMS. A medical user may not have time to document a patient specific classification, if there was no necessity for treatment of the patient. While executing daily documentation parameters export, it may be reasonable to use values of previous day as default if nothing was entered for the actual day. It is common for medical users just documenting patient status changes.

The best solution for that problem is establishing feedback circles between the PDMS and QMS to report important missing or wrong parameters of the patient documentation to the medical users. Because the adding or correcting of such necessary values implies additional work for them at the NICU, the quality of the patient documentation may increase and the incidence of missing or wrong data will decrease. If the QMS offers direct advantages for the users at the NICU the problem of missing or wrong documentation parameters for the system will disappear after short time using the system.

7.3.3 Problem: time when patient documentation is done

The immanent problem for data export from the PDMS that the patient documentation for specific time can be entered or corrected later is a wanted feature of any PDMS. The problem was named <Correction – Problem> and < Time –Problem> before.

Information and data about the patient actual for a specified time (“entry-time”) can be corrected and added (“real-time”) some defined time later. There is a time gap with a defined maximum between those timestamps which must be handled by the exporting system.

Regardless using frequent data aggregation or direct ad hoc data export there is only one solution for that problem. It is necessary to export the patient data of the same time range multiple times until no more changes or additionally data can be entered for that patient information time range. Patient information with no specific timestamp of validity (“entry-time”) like the date of birth of the patient can be changed and entered until the patient is definitely discharged. There is as well a define limit until patient data measured for a specific time, like patient weight, can be entered or changed. The documentation system does not allow any further changes after that limit (“correction-limit”). A common time limit configured within the PDMS would be 24 hours after the time of the event. The PDMS stores the time when the specific data was entered (“real-time” of data entry) together with the time of the data (“entry-time”). In the PDMS database changed or added items can be detected by the export process.

The solution concept shows overlapping data export executions of specified time interval, to update and correct already exported data. This concept must be also be provided by the QMS application. Depending on the defined “correction-limit”, the time the export itself is running and the data of the PDMS are available in its database the overlapping re-export time window must be defined. That can be 24 up to 72 hours.

Because no documentation values can be entered at the PDMS for patients not admitted at the NICU some users may perform short readmissions for those patients to enter some forgotten or correct wrong information about the patient. This behavior can lead to complex patient admission

handling for the PDMS data export system. The resulting additional problem belongs to the so named <patient admission identification – problem> which solution possibilities are described later.

7.3.4 Problem: performance of PDMS-data export

Reading patient information from PDMS databases with complex data storing structure and real large quantity of data can be rather slow. Some information about the patient like name can be read very fast from the systems database. But to get information about patient oxygen saturation may need several minutes, possible up to an hour, because there are huge amount of events about that information stored in the database.

To improve system performance for data export professional database software and potent hardware shall be assembled. There will be a limit for performance upgrade by the used IT environments.

Solutions to optimize the performance for data read from the PDMS database can be done within the export processes. It is profitable to use well designed temporary tables for the export to keep costly fetching of patient data in large event tables at a minimum. It is possible to concentrate readings from that extensive event tables to a single query copying the needed data to a temporarily used table. Optimizing the export queries using specific indexes and data sections can speed up the export as well. Good skills in SQL scripting and programming such export processes are necessary to implement a fast and effective exporting system.

Most database systems offer tools for query optimizing and measuring time expensive export processes. Some performance test will be required to develop a system which can achieve the required needs of the PDMS data export to QMS.

7.3.5 Problem: patient admission identification

The problem identifying correct patients transferred between units using the same PDMS was mentioned before.

It is helpful to use more the one HIT documentation system to identify correct admissions for the exporting system if possible. Those systems can be a Hospital Information System (HIS), a lab or radiological Information System (LIS, RIS) or any other Healthcare-IT system used at the unit. Crosschecking between the patient identifications and admission time stamps can help a lot to get the correct data matched.

There exists the problem for correct patient admission, readmission and discharge handling considering QMS requirements together with real PDMS documentation user behaviors.

It might be incorrect to use specified admission- and discharge-timestamps stored at the PDMS database to identify patient's admissions. The first data value from a connected interface (e.g. Pulse from monitoring) will show the correct start of the patient's file, because the patient can be entered to the system some time before physically admittance at the intensive care unit. The patient file should end with the last valid data from such interface for the patient as well. The discharge event timestamp of the PDMS may also be inaccurate. The file of the patient might stay admitted in the unit's system for data corrections or additional documentation of the patient some time after physically discharge.

A configurable method to define the handling of readmissions of the same patient is necessary. A time interval between discharge and readmission should be define to merge admissions of the same patient at the unit if the absence from the unit is shorter than defined. Minimal admission time required for patients should be defined to identify invalid admissions for PDMS data corrections or any testing.

The transfer to a different PDMS unit or readmission at the same unit will take some time after patient's discharge. The PDMS avoid admissions of the same patient at more then one unit at the time. This reasonable system restriction may force medical users at the unit to admit a "new" PDMS-patient which can not be identified by the system as already existing under special circumstances. That user behavior to "cheat" the PDMS can produce complex problems with patient identification and information retrieval for data export from the PDMS to QMS. The use of "test-patients" at the PDMS of the units can lead to some extensive patient census handling procedures.

Definitions within the control table of the export data mart, together with implemented potential patient admissions checks, will be needed to generate valid patient census and identification by the exporting system. For instance a specified name of a "test-patient" used at the NICU can be defined to be identified by the export system.

7.3.6 Problem: statistical information of specific time periods

Most statistical output is needed for different time periods. Therefore it must be defined how the data of patient admissions should be assigned to the selected time periods. For example: The items or diagnoses of a patient in the time period like one year is used for the statistic, if the patient is admitted in that year. If the patient was already admitted the year before but discharged the next year they should not be used. The data would be counted for the statistic of the prior year.

A configurable method to define the handling of time borders, which should be stored in the control table, for the specific statistics is helpful to generate correct output.

7.3.7 Problem: data-density of parameter from interfaces

For correct and valid export of patient data and information from the PDMS it must be known how continuous values from interfaces are stored at the PDMS.

The PDMS uses specified methods and algorithms to calculate a result of a time interval from the continuously received values from integrate interfaces. For example: The continuous Heart Rate (HR) value from the vital monitoring displayed there, is calculated every 10 minutes from a time interval from 5 minutes prior to 5 minutes after as a median of the values. Only the calculated value will be stored and displayed with the PDMS every 10 minutes.

It is essential for checking the premises of the QMS, to know how these parameter calculations are done by the PDMS. This information about the methods and calculations used by the PDMS must be documented and should be stored in the parameter definitions table of the export system.

7.4 General statements about PDMS-data export solution

During developing process all juridical specifications using real patient data must be achieved. De-personalization processes for the patient data can be established at the implementation task but can lead to undesirable development errors. Especially the correct patient identification and generating a valid patient census will be more complex using anonymised data.

Special development environment at the design and implementation process can be auxiliary. Any mistakes at that process will not harm the productive environment with real patient data. The transition of the export system with the data mart to the productive system will be an additional task at the end of developing processes after successful tests.

Software tools and programs used at data export projects to develop and implement the described PDMS data export solution and integrations of those systems to the IT environment are:

- Oracle™ environment: Versions 8, 9.2, 9i, 10g; including Worksheets, Enterprise-Manager, Integration-Manager, HTTP-Server, Grid-Control, etc.
- Microsoft™ Office
- PL/SQL-Developer Allround Automations ©
- Crystal-Reports 1.0 – 3.0 Seagate™; 4.0 – 9.0 Crystal Decisions™
- Active-Perl 5 programming language
- JAVA programming language
- Apache HTTP-Server
- SAS™ 8.2 environment including Enterprise Guide
- Toad of Quest Software

  and others

The decision using the ISM (Information Support Mart) or CDA (Clinical Data Archive) schema of the PDMS database depends on the requirements of the QMS. Some information about the patients and their treatment can not be achieved from the smaller and faster ISM schema. ISM contains of 34 tables and CDA uses about 300 tables to store the PDMS data and information. Information about value corrections, PDMS configuration, medical orders, patient bed and others can only be found at the CDA schema. If just one of that information is needed by the QMS the CDA schema must be used as data source. Because the ISM schema uses the CDA schema as data source patient values are accessible slightly sooner at the CDA.

The introduced solution concept has advantages and some disadvantages. The key benefits are high flexibility to adapt the system for needed PDMS-data of different QMS and the easy configuration of changing documentations. Avoiding multiple documentations by reusing PDMS data is the driving advantage for the users.

The outlined important communications between PDMS-users, QMS-users and system administrators are essential to keep the export system running correct. If these processes are not establishes well the periodical required adaptations will not accomplish with the result of invalid and incomplete patient data and information for the QMS.

The time delay of mostly more than 24 hours between PDMS documentation and the addressable information by the QMS can be a drastic handicap for some systems. This problem exists for any PDMS data access because of the possibility to correct and add values within the PDMS some time later. Any QMS using PDMS data must provide functions to deal with that documentation behavior.

Other disadvantages of the solution concept can be the need of extra resources including hardware, software and man power, for the export process. The definition and design task of the implementation process can be rather costly depending on the skills and experience of the involved persons.

The solution concept is evaluated in the next section by pointing out specific projects about success, working time, development process, customizations, complexity and user satisfaction.

8 Evaluation of the solution concept

The performance of the solution concept is valuated by describing development and operation of several projects over the last years. Some could never be satisfying realized and were aborted. Others project were implemented successful and did operate for a long time. Some of them are actually in use.

8.1 Specific projects implemented with the solution concept

All projects were develop and implemented with the designated solution concept on the described Philips CareVue PDMS environment using CDA or ISM schemas a database sources. The projects were realized by Philips Medical Systems Austria with consultant. Support and administration tasks are performed by the local IT-service of the hospitals with assistance from Philips and consultant. Some of the projects have product status and others are supporting systems as assistance work.

The depict concept to be evaluated operates with these projects. There are no publication restrictions and copyrights about the used data export concept.

8.1.1 Project: BMAGS-LKF

Site: Vienna General Hospital – Medical University of Vienna
Development: 1999
Implementation: 1999

needed patient admissions:

patients discharged from ICUs: adults – children – neonates;

needed data and information:

specific data-records according to patient-type at admission:
adult (older 15 years) – child (older 28 days) – neonate (younger 28 days) – vlbw neonate (younger 28 days and lower 1500 gm birth weight);
Admission-information; physiological scores; therapeutic interventions; discharge-information; exact definition of records needed for cost accounting by the Austrian health ministry including data-formats and value ranges;

system environment:

Philips PDMS CareVue CDM (Clinical Data Mart) Oracle™ database;
Source schema CDA (Clinical Data Archive);

QMS software:

Patient record checking routines at the controlling department of the hospital,
ICdoc© by büll informatik gesmbh [www.buell-informatik.at/de/icdoc.aspx]

Evaluation of development process:

The detailed and extensive parameter descriptions and definitions of the required data records, developed by an expert team for the ministry of health, were perfectly detailed for project definition and design process. High motivation to realize the data export to avoid multiple medical documentations came from the obligation to generate the defined electronic patient records for the ministry by the end of the year. The development process was supported very well by all involved groups of wards, hospital IT-department, controlling department and companies because the project contained advantages for all.

The system was implemented for 11 ICUs and 2 NICUs of the hospital. The data records of the patients were exported after their discharge. The clear deadlines of the project helped to be efficient completed.

Evaluation of system operation:

At system start just one ICU uses the application ICdoc to validate the exported patient record. All other units achieved a quarterly report from the controlling department with all wrong or missing patient documentations of the records. This poor feedback to the units raises some problems. It was demanding for users at the ICUs to correct parameters of patients which were discharged some weeks before. To improve that feedback circle for data corrections and validations ICdoc was installed at all other ICUs in 2001. Because the recording service for cost accounting of the ministry changed for NICUs in 2001 the data export for that units were excluded from the system.

The use of the QMS application at every ICU caused the request to get data of actual admitted patient at the units. In 2002 the export was extended for such admitted patients. That extension generated the mentioned problems about adding and correcting data at the PDMS after finished data export to the QMS. Redesign of the exporting procedures was necessary. That new feature of the system caused deterioration of performance at the exporting process. Further adaptations of the procedures to optimize data access were required to counter that problem.

Some periodic minor changes of the data specifications and export settings were done editing the definition tables of the system. In 2004 the extensive changes of the PDMS configurations to establish a general configuration for all PDMS-systems including ICUs, ORs (Operating Room) and ARRs (Anesthetic Recovery Room) could be performed with adaptations of that control tables of the exporting system. One single common PDMS-configuration facilitated the system accomplishment.

The changes of hardware and updates of the DB-system did affect the system slightly. The transformation of the data source to a new CDA could be handled by the system easily.

Because the ICdoc application was exclusively used as QMS frontend for the project some additional needed parameter from the PDMS were defined. Other items are documented with ICdoc instead of the PDMS. These major changes of the project definition originated a

complete redesign and new implementation of the project in 2007. The exporting systems were running parallel for a while before the replacement was performed. The actual system exports the defined PDMS patient data of 12 ICUs for the QMS applications ICdoc at the units. The parameters contain about 45 physiological values and measurements used for daily scoring systems. Intervention documentation is done with the QMS application.

The quality of the exported physiological data, primary from automatic interfaces integrated to the PDMS, was always very high. The quality of manual documented data by medical users could never reach that level. The PDMS data export project was adapted to perform there strength. Items with poor data quality at the PDMS and frequently necessary corrections are documented within the QMS application now. Mandatory fields and other control functions could be applied there because of the different intention of that application.

Actual status: operating
Operation period: 8 years now

Evaluation summary:

The detailed export definitions for specified discharged patients made the developing process straight and clear with marginal problems.

The strength of the concept was the high flexibility to cover PDMD configuration changes, parameter definition modifications and system moves easily. The completed BMAGS-LKF export solution was implemented at a pediatric ICU at the LKH-Medical University of Graz in 2000 with minimal adaption work. The high stability by recovering PDMS database shut downs and failures using the export concept was shown.

The concept weakness appeared after integration of actual admitted patients to the export project. The benefit using the specific ICdoc front end for export validations involved problems about the actuality of the exported patient parameters. For the users documentation corrections and additions became unclear. If items were changed at the PDMS it could not be seen at ICdoc until the next export process was finished. If items were changed at the QMS front end ICdoc the resulting data did not appear at the PDMS, because no writing back to the PDMS application DB by the export process is implemented and possible.

The actual version of the BMAGS-LKF export reacts on the strength of the system but changed documentation manner at the units.

8.1.2 Project: NICE-NL

Site: AMZ Maastricht, Academic Hospital Maastricht, NL
Development: End of 1999
Implementation: 2000

needed patient admissions:

patients at intensive care units; no classification;

needed data and information:

daily scores, physiologic measurements, ventilation treatment, discharge-information; definition of NL-ICU-scoring dataset [www.stichting-nice.nl];

system environment:

Philips PDMS CareVue CDM (Clinical Data Mart) Oracle™ database;
Source schema CDA (Clinical Data Archive);

QMS software:

Record checking routines at IT-department of the hospital; electronic patient-records submitted to the NL National-Intensive-Care-Database;

Evaluation of development process:

Parameter description and definitions of the required records were defined by the minimal dataset of the Netherlands National Intensive Care Evaluation (NICE) organization. NICE comprises a continual and complete registration of all patients admitted to the ICUs of the participating hospitals in the Netherlands. The system was rather similar to the BMAGS-LKF in Austria, but the quality of the system specifications was worse.

The motivation for the project came primarily from the IT department of the hospital. Only sparse communication between medical users and the developers was established.

Big parts of the developing process were done in Vienna. Tests and integration tasks were realized during short visiting periods at the site. Instructions for the users at the IT-department were given at system delivery at the AMZ Maastricht.

Evaluation of system operation:

In 2001 the hospital did major PDMS reconfigurations which could easily be covered by editing the control tables of the export system. The whish to export actual admitted patients with the system appeared at that site as well. In 2002 the PDMS database source schema was changed to ISM which determined some modifications of the export processes and their control tables.

The week communications between the PDMS users and the IT-staff as export system users caused several misunderstandings and misinterpretations between documented patient data and exported patients records.

Actual status: unknown
Operation period: at least 4 years

Evaluation summary:

The specified system demands for the defined required patient records export could be effectively implemented with the presented export concept.

The satisfying flexibility of the concept was shown again by covering big PDMS configuration adaptations easily.

The use of the system concept to export actual documented patient data let pop up some problems for the system.

The detailed export definitions for specified discharged patients made the developing process straight and clear with marginal problems. The necessity of well established communications as feedback circles between PDMS-users and QMS-users was recognized clear within this project.

8.1.3 Project: MONI

Site: Vienna General Hospital – Medical University of Vienna
Development: 2004
Implementation: 2004

needed patient admissions:

Actual admitted patients at intensive care units of the hospital including NICUs;

needed data and information:

Admission-identification-information; daily patient data with infectiological relevance: Antibiotic medications, body temperature measurements, catheters information, body intake-output, scores, laboratory values, other parameters like vital sights - not specified detailed;

system environment:

Philips PDMS CareVue CDM (Clinical Data Mart) Oracle™ database;
Source schema ISM (Information Support Mart);

QMS software:

MONI® Microbe and infection alert, monitoring, and surveillance systems; Knowledge-based identification and automated monitoring of hospital-acquired infections as cockpit surveillance; medexter® [www.medexter.com];

Evaluation of development process:

Documented infection relevant parameters of actual admitted patients at ICUs were needed to develop the described MONI-system for knowledge-based identification and automated monitoring of hospital-acquired infections. There was no clear definition about the required parameters. During development and operating process the parameter were defined in specified groups. The scientific development was done by the clinical institute for “Hygiene and Medical Microbiology” and the unit for “Medical Statistics and Informatics” section “Medical Expert and Knowledge-Based Systems” of the Medical University of Vienna. The motivation was to develop a system for practical use at the ICUs and cockpit surveillance at the institute for hospital hygiene with the scientific developers of the university.

The PDMS export system was designed maximal flexible to cover further requirements of the monitoring system. Microbiological patient data were provided with an extra exporting system using none PDMS data sources.

PDMS data from 12 ICUs and 3 NICUs of the hospital are exported to the MONI data mart schema. The development process is not finished yet, because the exporting system is needed to develop the knowledge-base with real online patient information.

Evaluation of system operation:

The required patient data for the development of the knowledge-base system changed periodical and could be easy fetch with definition and control table adaptations. The solution concept could handle that definition changes. The extension to include neonatal units with a completed different PDSM configuration could be covered rather easy.

The unclear definition how long patient data shall stay at the export data mart leads to problems of export performance. The knowledge-base development needed to use the same information of patients repetitive. Therefore the data mart tables were cloned to hold either data for actual operating or development. This could solve some problems about the unclear data usage.

There is no communication between the QMS and the PDMS users established yet. The QMS is at the moment exclusive used by the Hygiene Institute of the hospital. Problems about the time delay because of data corrections do not harm the system at the moment.

Actual status: operating
Operation period: 4 years and development ongoing

Evaluation summary:

The solution concept could again prove the flexibility strength on changing parameter and export specifications. The not existing communications channels between the QMS and the IC-units avoid serious data validations.

Problems about corrections and completions of patient documentation at the PDMS will appear, if the QMS is used at the ICUs. Some solutions about that must be found.

Connecting microbiological patient data from different data source with the PDMS data is no trouble for the system concept.

8.1.4 Project: Neonatal-discharge-Report

Site: LKH-Medical University of Graz, Department of Neonatology
Development: 2003
Implementation: 2004

needed patient admissions:

discharged and near to discharge patients of the NICU.

needed data and information:

Admission-information; discharge-information, laboratory values at admission and discharge, ventilation days, specific events, specific medications, specific care interventions, nutrition at discharge, body measurements;

system environment:

Philips PDMS CareVue CDM (Clinical Data Mart) Oracle™ database;
Source schema ISM (Information Support Mart);

QMS software:

Microsoft Access Application to view and print reports;

Evaluation of development process:

The discharge-report was defined at the NICU coevally with the PDMS implementation and configuration. The unit did not use any PDMS before. At several meetings with the leading physicians of the unit, which was the users of the QMS, the report specification was defined in detail. The PDMS configuration was adapted to the needed patient documentation parameters of the QMS. An extra input field was configured to prepare patients for discharge. That field forced the export process for the patient.

The creation of the specified report was motivated by including existing external diagnoses data sources of the patients. Because users of the QMS were users of the PDMS, data validation could be done directly.

The design of the QMS data mart and implementation of the export procedures were done together with development of the QMS front end. The implementation of the QMS application with other and possibly more solid and suitable software was discussed, but refused by the users.

Evaluation of system operation:

The calculations of the requested summaries for the neonatal discharge report were working stable and did not change until now. Only very few configuration changes must be covered.

The Microsoft Access front end application produced performance problems caused by the used ODBC-data connection to the data mart. The main reason was weak network performance with repeated failures.

In 2005 a second Microsoft Access application was developed to generate newborn growth charts. The QMS solution was widened to export daily body measurements like length and weight of all actual admitted patients. Similar performance problems of same reasons appeared with that additional application.

The QMS solution with the front end application was implemented at the 3 NICUs at the Vienna General Hospital – Medical University of Vienna in 2006.

Actual status: LKH-Graz – unknown; Medical University of Vienna operating;
Operation period: 4 years now;

Evaluation summary:

Again the flexibility strength was seen by easy transforming the system to a different hospital environment and PDMS configuration.

The PDMS documentation corrections and completions problem did not trouble the systems export solution. Summary information about the patients was calculated over the complete admission period. Only very few treatments and therapies are documented with the PDMS short time before discharge of the patient. The body measurements of actual admitted patients vary very slightly a day. The small changes are of no interest and can hardly be seen on a growth chart for a patient over month.

The integration of a separate data source for the QMS could be solved easy with the PDMS data export concept.

There are still major problems with the MS Access front end usage. The implementation of a better, may be web based, QMS application could advance usability of the complete system at lot.

8.1.5 Project: FFP / DRG / OPS

Site: University Hospital Tübingen (UKT), Medical IT (MIT), Germany;
Development: 2006
Implementation: 2006

needed patient admissions:

OR and ICU patients, discharged and admitted;

needed data and information:

Patient-information, OR-information, events, infusions, medications, diagnoses, medical treatment, laboratory values, physiological values for scores, scores;

system environment:

Philips PDMS CareVue CDM (Clinical Data Mart) Oracle™ database;
Source schema CDA (Clinical Data Archive); Administration with TOAD;

QMS software:

Interfaces to existing reporting tools and evaluation databases and tools;

Evaluation of development process:

The hospital did export the patient data and information from the PDMS with different proprietary developed programs. The exporting processes accessing the CareVue ALLBASE database with actual data were implemented over years. The complex dependences of data and processes caused sophisticated adjustments and maintenance task with documentation changes. That problems created corrupted databases and the data export processes could not generate the required records any more.

A complete PDMS database recovery was started. The project aim was to implement the described data export solution to generate the already integrated records from the PDMS to the existing evaluation tools as soon as possible. The proved flexibility and configuration strength of the concept were exigencies for the project.

The "frozen" PDMS database schema CDA of the hospital was delivered to Vienna where the design of the solution data mart and implementation of the export processes was started. The definition tasks for the design process were elaborate because of the distance between the site and the development place. The great challenges were to generate the complex infusion items and the medication information linked to external data sources.

At repeated site visits the solution system was implemented with instructions and trainings for the Medical-IT staff of the hospital. The project was completed by them at the site with some advices and support from Vienna.

Evaluation of system operation:

The project solutions together with the instructed concept for further enhancements produced an appropriate tool to fulfill the requirements of QMS evaluation tasks. The hospitals Medical-IT used the PDMS data export solution concept with further developments successful.

Communication processes between PDMS users and the QMS at the MIT were already established at the prior used PDMS data exporting system.

Changes of PDMS configurations and additional parameter integration could be covered local. There was no need to export time relevant data from the PDMS because the deployed evaluation tools were used for retrospective analysis.

Actual status: unknown;
Operation period: at least 2 years;

Evaluation summary:

The presented solution concept was used for emergency interventions at this project. It was shown that the system could be adapted into an existing environment of complex patient data evaluations rather fast and easy. The high flexibility and adaptation strength was essential to supply QMS requirements

Performance problems and PDMS documentation corrections and completions behaviors were of no relevance because the data evaluation system was used retrospective. For example the summary report of all applied Fresh Frozen Plasmas (FFP) as high cost relevant medical treatment at the hospital was generated quarterly.

8.2 Classifying QMS at the NICU to be suitable with the solution concept

Some other projects at the NICU and other sites were implemented using the presented PDSM data export solution for QMSs. There are no further findings about the solution performance at those projects.

QMS at the NICU which can reuse PDMS data exported with the solution concept:

- External quality benchmarking: ASDI, Vermont Oxford DB;

- Ward statistics
- “Scientific Database” for quality measurements
- Patient admission reviews

QMS at the NICU which can partial reuse PDMS data exported with the solution concept with some restrictions because of the time relevance of parameters:

- Infection monitoring: MONI, RALIS, NEO-KISS
- Knowledge-based export system: VIE-PNN
- Data visualization system: VIE-VISU

QMS at the NICU which can not reuse PDMS data exported with the solution concept because of accurate time relevant need of patients data.

- Ventilation support system: VIE-VENT, close-loop oxygen control;

QMS at the NICU for ward specific Guidelines/Protocols and SOPs can reuse PDMS data exported with the solution concept depending on the need of time relevant patient data and information.

8.3 Limitations of the solution concept – evaluation summary

Also the PDMS data export system using the presented solution concept is suitable for some QMSs there are clear limitations of the system operations.

The shown skills of the solution concept are high flexibility to suits different demands of QMS primarily used for retrospective evaluations. The possibility to easily adapt the exporting system on accomplished changes of patient documentation is a proved strength of the concept. But it is important to recognize such changes. Therefore some communication pathways between PDMS users and QMS users are required. The possibility to customize the export system for different system environments is another demonstrated strength of the solution concept.

Problems with the PDMS data export solution appears involving admitted or recently discharge patients. The possibility of the PDMS to correct or add data causes the need of recalculated and re-exported solution records for the QMS. Likewise the QMS must offer techniques to re-import such records for already existing data.

The time it needs for documented patient data to be accessible by QMS can as well be a limitation for the use of the PDMS data export concept. This time limit is defined by the polling of the PDMS data to the PDMS database schema, the export process itself and the possibility to enter data for items some time ago at the PDMS. That delay time has an estimated range from 12 to 36 hours after the entering of an item.

To implement the solution concept for data export data processing skills and good knowledge about the database schemas of the PDMS is required. Knowledge about the PDMS documentation

and usage is needed as well. Programming experiences are necessary to implement the export procedures.

There are limits to integrate configurable rules and calculations to generate required parameters for the QMS. A flexible and more extensive concept for those functions would lead to an editable rule-engine used at knowledge-based systems. The calculations and mappings used by the export system should be relatively easy.

According to [Table 12] “QMS premises and recommendations” in section 6.1, all required definitions and recommendations must be achieved to facilitate a QMS with information and data from the PDMS documentation. If the required data dense for parameter calculation at the QMS can not be reached the limit of PDMS data export system is met.

Not available information can not be exported. The technique to generate required information about patients combining several other documented items can be used but this method is very limited.

The wish to get complete datasets of required patient information without entering the necessary data is sometime expressed by the users. This wish can of course impossible be fulfilled. The demanded patient data must be collected by users or interfaces and be receivable for export.

The dream of some physicians to generate medical reports after discharge of patients automatically can hardly be performed by any PDSM data export system. Validations and checks done by the doctors are required to get such reports. PDMS data summaries can help them to compose the medical documents about the patient admission. A complex expert-system would be needed to replace physicians generating those excerpts.

The presented solution concept can facilitate QMS exporting PDMS data from the patient documentation with doing some calculations and parameter mappings. It does not support the QMS with parameters calculated by complex knowledge-based expert system.

9 Future Outlooks

More QMS applications to be used at intensive care will be developed in near future. There are many research projects attended to such systems. Especially the integration of computerized SOPs (standard operating procedures) and CPGs (clinical practice guidelines) into clinical workflow at ICUs will be an important task. Nearly every newly developed PDMS/CIS provides functions to integrate such systems.

Data exchange and system communication including user interfaces will become fundamental requirements for such HIT at medical practice. Easy maintainable and flexible concepts for such integration procedures of systems used in connection to PDMS/CIS are essential. The formation of some standard procedures and connection concept, considering the mentioned problems of PDMS patient documentation, will be reasonable. The independent commercial and scientific process of system development does not raise hope for early implementation of such standard procedures.

The public and governmental demands on external quality control and medical process management may put some pressure on the developing process. But in the past such requirements normally leaded to additional documentation tasks for medical personal.

Now and in near future PDMS/CIS data exchange will be needed to bring information about patients to physicians not present at the patient. Those applications of telemedicine start to be used more common. Many additional problems will rise for those systems to retrieve actual PDMS/CIS from ICUs. Technical environments and security concepts can not perform such sensitive, extensive and demanding data transfer necessary for intensive care at the time.

Actual commercial PDMS/CIS applications can handle data writing processes determined by additional QMS. Such procedures to write data calculated at QMS application back to PDMS/CIS databases will be even more complex to be implemented. Dependencies on performed values and used patient data may produce unstable system conditions. It should stay in mind that high reliability is primary requisition of PDMS/CIS HIT used at intensive care.

The sensible working areas of such systems determine the extensive developing process and the rarely implementation at clinical practice.

Visualization tasks and improvement on HIC (human-computer-interaction) for HIT used at intensive care will become important development and research projects of near future.

10 Conclusions

The presented system and concept for PDMS data export to integrate and improve QMS applications at intensive care is very flexible and well maintainable. Communication feedback mechanism must be established between PDMS users and the users of the QMS. It was shown that the system and its concept work well at individual intensive care units and the introduced NICUs. Support for such system integration procedures is required at the units.
A motivated team at intensive care units must invest time and resources to integrate QMS into clinical routine processes. Information about the PDMS documentation behavior is required. If the QMS application generates advantages for medical staff and patients at the unit the necessary exertion for PDMS data export and system integration process will accomplished successfully
Information and data about patients for most QMS exist only at the units where the patients are treated. But the medical teams at ICUs barely have resources for additional documentation. Any QMS requires its specific kind of information and patient records, sometimes rather similar to documented data at the PDMS. But it may be essential to adjust the PDMS configuration for documenting the required information about patient for QMSs. Compromises in intention of use for the documented items should be found. Items may be more suitable for the QMS than, but could be accepted for "normal" documentation as well.
To deal with subsequent data corrections and missing essential patient information, both used systems for PDMS data export and QMS data import must provide functionalities to re-export and re-import data. The user communication process can call attention on missing essential parameters at documentation.

Calculations and aggregation rules for required patient parameters can be done at the PDMS data export process to the QMS. Those methods are limited. QMS data import functions could provide such calculations, rules and mappings as well. Some QMS provides rule based knowledge systems for data analysis and information finding. It can be hardly told at which state of the patient "raw" data transformation process from documentation to QMS information such methods should be placed.
Calculating information from patients "raw" data needs knowledge about the documentation behavior and data acquisition at the units in any case.

The demanded computerized SOPs and CPGs integration into medical workflow will need elaborate methods for data and information exchange to the patient documentation system. Enhancements of such concepts for QMS integration at PDMS will be needed. Further research projects and PDMS developments will be required to bring such auxiliary procedures to routinely medical practice successfully. The demand for helping computerized applications exists at intensive care with existing information overload at the point of care.

The goal of such systems should be the transformation of many redundant and according information and patient data to clearly recognizable ranked information. Enormous work on such demanding solutions will be required for next decades.

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