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User requirements for data systems in anaesthesia and intensive care

First edition

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Preface

This document has been prepared as part of the pilot project on Data Management in Anaesthesia and Intensive Care (DMAI). A project on DMAI was originally proposed by Nordmedtek, a Nordic cooperative organ for medical technology. At the ad-hoc workshop on Patient Data Management in Anaesthesia and Intensive Care in Helsinki, November 3–4, 1986, representatives of leading Nordic hospitals decided to launch the project and to begin with a pilot study. The pilot study was financed by Nordisk Industrifond, and its main objectives was to create a first version of Nordic user requirements for data systems in anaesthesia and intensive care. The main project is planned to consist of individual subprojects which demonstrate the use of modern data technology in the field of anaesthesia and intensive care.

The purpose of this first edition is to start discussion of user requirements for DMAI. The requirements will be revised and developed further during the main project.

This draft has been prepared by the pilot study working group: Pertti Nikki, Professor, Helsinki University Central Hospital (chairman); Sverre Grimnes, Professor, Rikshospitalet, Oslo (secretary); Aarno Kari, M.D., Kuopio University Central Hospital; Gunnar L. Olsson, M.D., St Görans Hospital, Stockholm; Hans B. Rasmussen, M.Sc., Rigshospitalet, Copenhagen; Björn Zarén, M.D., Uppsala Academic Hospital.

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1. What is data management in anaesthesia and intensive care (DMAI)?

The ultimate goal of automated data management in an operating room or an intensive care unit is to facilitate patient care. This is achieved by improving documentation of patient care and the quality of the available patient data, reducing the manual registration workload, and speeding up administrative routines.

Data management in anaesthesia and intensive care (DMAI), as it is understood in this paper, comprises two main functions:

1. handling of medical data,
2. handling of administrative data.

By medical data we mean all data necessary for treating the patient, such as measured physiological data, therapeutic data, and medical patient records. A list of typical monitored parameters in anaesthesia and intensive care is given in Appendix 1. By administrative data we mean all data that is necessary for running the unit, e.g. patient census data, work lists, economical data, or data related to quality assurance of patient care.

The main functions can be performed by one single data management system or separate systems. In the latter case, the administrative services may be obtained from the general hospital information system without a connection to the departmental medical data system. However, truly effective departmental systems would have such connections.

Problems directly related to measurements and monitoring – such as the question about the physiological parameters that need to be monitored and the ways in which they should be measured – will not be addressed by these requirements. Consequently, patient monitors and other measurement and therapeutic devices are not considered here to be actual parts of the DMAI system.

There are, however, several possible ways of dividing the necessary data management functions between different hardware and software components of the total measurement and data management system. For example, certain functions, such as the generation of alarms and trend representations, may be either wholly included in the patient monitors or partly performed by the data system. The physical location of such functions should not be significant from the user's point of view.

The following functions are typical for a DMAI system:

- automatic data collection from different monitoring and therapeutic devices;
- automatic input of laboratory results;
- manual input of measurements and observations at bedside;
- manual or automatic input of administrative patient data;
- automatic calculation of derived parameters;
- trend representations of measured and calculated data;
- alarms or indication of abnormal changes;
- current prescription lists and follow-up of prescribed care;
- data reduction for storage and reporting;
- report generation;
- advanced administrative functions;
- local electronic mail.

The following functions may also be needed, mainly for research purposes:

- storage of real-time waveforms;
- long-term storage of accumulated or selected patient data;
- statistical analysis functions.

2. General requirements and preconditions

2.1. User-friendliness

The DMAI system must be well adapted to the end-users' needs and duties. It must be efficient to use for experienced, properly educated users and simultaneously easy to learn for novices.

2.2. Superiority over manual systems

The system must provide an overall advantage over a manual system with respect to such aspects as

quality of data, ergonomy, staff workload, and reduction in administrative workload.

2.3. Open architecture

System design should aim at an architecture open to patient monitors, therapeutic devices and different workstations as well as to other hospital computer systems. The data system should not be dependent on any particular configuration of monitored parameters. Even if the system is designed as a stand-alone system, the possibility of later connection to other data systems should be kept in mind.

2.4. Compatibility with different patient monitoring and therapeutic equipment

The system must accept international or de facto standard digital interfaces, such as the RS232 interface. Hospitals should only buy anaesthesia and intensive care monitoring equipment with digital interfaces. Infusion pumps and ventilators which have digital interfaces should be preferred to those without. It may also be necessary to use analogue interfaces if older monitoring or therapeutic equipment is connected to the system or if devices with digital interfaces are not readily available.

2.5. Software portability

It is strongly recommended that the system software be portable, based on operating systems like Unix or MS-DOS, and that it should use commonly preferred programming languages.

2.6. Flexibility

It must be possible to initially configur the necessary measurements and data system functions according to local specifications so that the system can adapt to the particular administrative or medical functions of the unit.

As their needs change, users must be able to make simple extensions and modifications to the system (e.g. to add new measured or derived parameters and change units, reference values, or trend scales).

When new functions are needed, they should be programmed by the system developer or his designee according to mutually agreed conditions. If such an agreement on further system development does not exist, it must be possible for experienced hospital staff to make some changes. In that case, program source files should be available to the hospital.

The system must allow for an increase in the number of workstations, for example, when new patient beds need to be connected.

2.7. Data security

The system must include necessary log-on and password systems and other means for data access restriction so that local legal requirements can be fulfilled. Special attention should be paid to the location and data access rights of different workstations.

2.8. Short response times

In normal clinical work, especially at the bedside, the interactive response times of the data system should be made as short as possible. When selecting from a menu containing patient data, the next screen should be available in no more than one second after the moment of selection. Longer response times can be acceptable for high-resolution screen graphics, running special programs, or retrieving large amounts of data.

2.9. Reliability and fault tolerance

The maximum failure rate of the data system, as well as the ability of the system to tolerate temporary power losses and different types of computer faults (e.g. processor, interface and disk faults),

must be stated by the manufacturer.

Measurements must not be affected by faults in the data system, and a fault in a particular measurement device must not disturb data collection from other devices. When automatic data collection stops, the system must warn the users immediately so that manual data collection can be started.

Data loss during failures must be minimized by storing all critical data automatically in two independent devices. In this context data can be considered critical if it is not stored in electronic form or as a hard-copy in any other place in the same hospital. It is unacceptable for there to be any loss of data stored before the system failure.

The system should recover from power losses automatically and from computer failures by simple recovery processes managed by the hospital staff.

2.10. Compatibility with clinical environments

The hardware of the data system must be specified for use in the ambient conditions (e.g. temperature and humidity) prevailing in intensive care units or operating rooms.

All parts of the system which are located in a clinical environment must be easy to clean. The manufacturer should state clearly any special precautions necessary for the protection and cleaning of these devices.

2.11. Patient safety

Connections between patient monitoring and therapeutic equipment and the data system must not reduce electrical patient safety in any way, either during normal operation or under failure conditions. DMAI hardware must comply with national safety regulations.

3. Requirements for the system configuration

3.1. Hardware configuration

The hardware configuration of a DMAI system should consist of

- interfaces to patient monitors and other measurement and therapeutic devices, as well as the necessary computer interfaces and communication components;
- all conventional hardware components of the computer system;
- different types of workstations:
  1. bedside workstations,
  2. doctor's workstations, nursing workstations, administrative workstations, etc.

A workstation consists of a display screen and input/output devices (e.g. a keyboard and a printer or a plotter). Different workstations may have different software functions, which should have a clear relationship with the functions of patient care. For instance, it should be possible to enter and review at bedside all data related to the monitoring and therapy of an individual patient.

The data system architecture should be sufficient to allow for distributed parallel processing. The benefits and disadvantages of microcomputer networks versus central host computers should be outlined by the system developers. Cost per patient bedspace, user maintenance and system downtime as well as possibilities for system expansion and modification should all be considered.

3.2. Software structures

3.2.1. Operating system

The operating system controls the allocation of computing resources, allowing the computer(s) to be used by the database management software and application software.

The data system should be based on a commonly used operating system such as MS-DOS, Unix, or Xenix. The operating system should preferably be capable of multi-tasking.

3.2.2. Database management system

All clinical and administrative data related to patient care are sorted and stored by the database management system (DBMS). Responsibilities of the DBMS include:

- data storage;
- data retrieval;
- data protection;
- data sharing.

The DBMS should provide rapid and efficient retrieval of data. Data must be retrieved in a variety of combinations, allowing the user to ask specific and general questions about patient care.

The DBMS should provide assurances through protection mechanisms that the data it maintains is consistent. Redundancy and backup facilities should be available to insure that the database can be reconstructed in the event of hardware failure.

The DBMS should allow concurrent access to patient data by multiple users. The system should insure that at most one user (or automated source) is able to 'lock' a record for the purpose of updating it.

3.2.3. Application software

Application software refers to the utilities which facilitate the tasks of patient care. The application generator should use a high level but simple computer language (e.g. C). The utilities should provide for:

- data capture, analysis, display and printing;
- routines for screen prompting or automatic entry of data;
- calculations of derived parameters from entered measurement results;
- report generation;
- assistance in care planning;
- administrative and secretarial functions;
- communications (such as local electronic mail);
- research functions and other special applications.

All application software must be properly tested and documented.

Types of data and patient care can be grouped into a limited number of categories. This organization results in a main menu selection with several submenus. Medical patient data should be separated from purely secretarial and administrative functions and technical system management functions.

Secretarial and administrative functions should, among other things, facilitate patient traffic (admission, discharge, transfer, and readmission) and permit manual or automatic entry of patients' demographic information.

In the actual patient data section, submenus related to different groups of physiological and therapeutic information (haemodynamic, respiratory, metabolic, and neurologic parameters; laboratory data, description of anaesthesia, medications, fluid therapy, etc.) should be provided. A submenu for patient assessment should allow for entry of information about physical examinations and observations. Clinical record and reporting facilities should permit entry of information about diagnoses, procedures, consulting physicians etc., and generation of daily and summary clinical notes and reports.

Manual entry and manual change of data must be allowed for within each menu item containing medical or administrative data. For automatically collected data, the possibility of manual verification of data may also be necessary.

4. Requirements for data inputs

4.1. Automatic data collection from different monitoring and therapeutic devices

In principle, all data measured automatically should also be registered automatically. In addition to patient monitors, ventilators and infusion pumps should also be connected to the system if possible.

4.2. Automatic input of laboratory results

Laboratory results should be obtained automatically (e.g. via a connection to the central laboratory computer or to chemical analyzers in the unit).

4.3. Manual input of measurements and observations at bedside

Users must be able to enter results of manual measurements and other current patient data at the bedside. The manual input procedure should preferably be no more time-consuming than the procedures used before the introduction of the electronic data system. Means for indicating time when therapeutic actions are taken and quality of measured data may be required.

Entry time and user identification should be registered automatically for each manual entry. The user must be able to specify the actual moment of measurement or observation if the entry is made later.

It must be possible to make corrections both immediately (before the data is sent to the system) and later, when an error is noticed. In the latter case, the original data has to be kept for legal reasons.

4.4. Input of administrative patient data

At least the most important administrative patient data, such as name, main diagnosis and time of arrival, must be available from the system. This information might be entered at a nursing workstation or a doctor's workstation, i.e. not necessarily at the bedside. Some of the administrative patient data may be obtained automatically via a connection to the general hospital information system.

5. Requirements for patient and administrative data processing

5.1. Automatic calculation of derived parameters

All necessary haemodynamic, respiratory, and metabolic parameters should be calculated automatically by the data system. The parameter selection should be configured according to the needs of each intensive care or surgical unit.

Some typical derived parameters are given in the parameter list in Appendix 1.

5.2. Trend representations of measured and calculated data

All quantitative data should be represented as trend graphs, available both on the screen and as print-outs. Users should be able to choose sampling intervals and time scales for the trends. Trend lengths up to one week may be necessary in intensive care. Short-term trends given by patient monitors need not necessarily be available from the data management system.

5.3. Alarms or indication of abnormal changes

Ordinary alarms, activated when a physiological variable exceeds certain limits, are usually displayed on the patient monitors. The data system may also provide alarm lists and trend analysis functions, which lead to more sophisticated alarms or indication of abnormal changes in the patient's condition.

5.4. Current prescription lists and follow-up of prescribed care

Lists for orders concerning medication, fluids and nutrition, laboratory tests, ventilator adjustments etc. may be needed on the screen and/or as print-outs. The system may also provide information and suggestions which help the doctor when making prescriptions. Confirmation of performed therapeutic actions may be entered into the system by nurses.

5.5. Data reduction for storage and reporting

The most relevant information should be stored for later retrieval in the form of simple records for each patient. Different levels of data reduction may be necessary e.g. for data collected during the last 24 hours and for older data.

5.6. Advanced administrative functions

Advanced administrative functions, such as administrative statistics, information about personnel work-load and space utilization, and support for patient scheduling and supply management, may be included in the data system. A separate administrative workstation should then be reserved for these functions.

5.7. Report generation

At least simple medical reports, such as anaesthesia records, should be obtainable from the system as print-outs. The layout and contents of these reports must be initially configurable by the users.

The reports generated from patient data serve a number of different functions: they document the severity of illness, they document the therapeutic intervention and the therapeutic response, and they assist the medical staff in decision making. Additionally, purely administrative reporting facilities may be needed to produce management reports, work lists, billing reports, quality assurance reports etc.

6. Requirements for system outputs

6.1. Displays

Displays must enable effective data viewing. System output data should include text and numerical data (reports, tabular form data, etc.) as well as graphics (trend graphs, possibly also real-time waveforms). Users should be able to configur the contents of the screens so that different data can be grouped in the most efficient way for each type of patient.

6.2. Print-outs

The users must be able to print out any data contained in the system, at least as hard-copies of the screen. Certain relevant data are regularly printed out in the form of special reports. Flexibility is desirable in defining the contents and layout of the reports.

6.3. Storage and archiving

The hospital and the system developer should agree on the contents, saving period and storage medium for short-term archives. The legal requirements of the relevant countries should be taken into account.

7. Requirements for the user/system interface

The acceptance and usefulness of patient data management systems depend greatly on their user interfaces. There is little practical knowledge about the advantages and disadvantages in clinical work of, for example, different means of manual data entry and item selection from a menu. Accordingly, experimental installations for testing different user interfaces should be set up.

7.1. Ergonomy

The data input/output devices must be well adapted to different working situations, including the user's working position. Special input devices to make data entry fast and easy should be considered.

High display-capacity screens, enabling efficient windowing techniques, may be required. However, in operating rooms or other places where space is limited, smaller displays are preferable. Large slave screens may be required in operating rooms. Colour should be used to increase the clarity of the data. Other forms of highlighting (shading, different levels of brightness, etc.) may also be necessary.

Hard-copies of the screen should have the same resolution as the display. If colours are required, they should appear in print-outs as they do on the screen, if possible. For black-and-white print-outs, some other means are necessary for indicating the

difference between the trend graphs of separate variables that are represented together.

Acoustical noise generated by DMAI hardware (e.g. printers and processing units) situated in patient or operating rooms must be low enough not to disturb medical staff or patients.

7.2. Using menus

The menu tree must be constructed so that the most often used routines can be quickly accessed. Different ways of going through a menu may be needed for different users. Because temporary personnel from other departments may have to use the data system, the menu structure should be simple and logical. On the other hand, shortcuts, such as special function keys, should be provided for experienced users.

7.3. Manual data entry

Manual data entry must be minimized because it is the most time-consuming phase of using the system.

When selecting the means for data entry, ergonomy – for instance, the user's working position – type of data to be entered, and ease of cleaning the input devices must be taken into account.

8. Requirements for special research functions

8.1. Storage of real-time waveforms

It may be necessary, particularly during research, to store selected amounts of real-time waveforms such as ECG in digital form. Because quickly-changing parameters require high sampling rates, the stored periods should usually only cover special events.

8.2. Long-term storage of accumulated or selected patient data

A database containing patient data may be needed for research purposes and/or for archiving the data records of patients who have left the unit. This database should be stored on a separate medium, such as floppy disks, a separate hard disk, or an optical disk. The data management system should be capable of retrieving the patient records. Provision should also be made for passing data into larger storage facilities in hospital-wide computer systems.

8.3. Statistical analysis functions

It should be possible to use reduced sets of patient data for statistical analysis for administrative and research purposes. The user has to define in advance the sets of data which are to be stored and analyzed. The data management system should arrange the data sets into a form readable by a statistical package defined by the user.

9. Requirements for knowledge-based subsystems

The decision rules of possible knowledge-based subsystems (KBS) of the data management system should be thoroughly tested and assessed in different hospitals.

9.1. Intelligent alarms

Coordination and quality control of alarms may be achieved using knowledge-based system(s) embedded in the data system or with measurement devices. Such a subsystem requires an on-line interface to patient data.

9.2. Other knowledge-based subsystems

Other knowledge-based subsystems, which assist in the ordering of medications or the planning of

anaesthesia, fluid therapy, or respiratory therapy, may be included in the data management system. These expert systems can be either criticizing or consulting, but the final decisions should always be made by the user.

10. Requirements for local communications and links to other data systems

10.1. Local electronic mail

An electronic mailbox with notes and instructions can function as a communication channel between different working shifts and different personnel groups of the unit.

10.2. Links to other data systems

A link to the hospital's laboratory data system is necessary, at least for an intensive care data management system. Additionally, a connection to the general hospital information system or network may be needed for transfer of administrative patient data and statistical information. Links between different departments, such as the surgical department and intensive care unit, may be necessary for consultations and automatic transfer of reports (e.g. anaesthesia, surgical, and radiological records) and other patient data.

When planning such links, special attention should be paid to data security. The capacity of the hospital communication network should be checked. A precondition for communication between different data systems is that the data are well modelled so that each data item is identically defined and used in all subsystems.

11. Other requirements

11.1. Transfer of data system knowledge to the hospital

There must be a project support team with medical as well as system engineering knowledge in the hospital. The support team should initially be selected together by the hospital and the system developer so that all necessary knowledge about running, maintaining and upgrading the system can be transferred to the hospital. The goal is to make the hospital self-sufficient in this respect after the cooperative development phase.

11.2. Definition of responsibilities for the system

Responsibilities for system management, maintenance and upgrading must be defined. For small hospitals it may be most feasible to buy the system as a package, with all further responsibilities to be held by the system developer. Large hospitals may find it necessary to share the responsibilities and to have some programming support done by their own technical staff.

One of the users should function as a system manager. A person responsible for the software must be nominated by the hospital and should be acceptable to the system developer.

11.3. Education

Teaching material must be prepared as a part of the system development process. Facilities such as phantom beds and phantom patient files are useful for student and user education. Advanced education should be arranged for selected users and technical personnel.

11.4. Documentation

All application software must be properly documented. At least the following information should be given:

- name of program and date of version;
- name of author(s) and contact person(s) or organizations;
- whether the program has been accepted by any authorities;
- information about the distribution medium and form (e.g. source or object code) of the program;

- clinical purpose of the program;
- underlying models and principles;
- necessary input data (e.g. measurement results) and method of data acquisition;
- algorithms, calculations performed, etc.;
- results produced by the program;
- hardware requirements and limitations;
- detailed operating instructions with examples.

There must be detailed documentation of all interfaces.

11.5. Maintenance

Periodic maintenance routines, for which the users are responsible, should be clearly defined. Updated versions of system and special software should be provided by the system developer or by the hospital's own engineers responsible for software.

11.6. System diagnostics

Self-diagnostic procedures and test functions should be provided and clearly documented. It is desirable in failure situations that the system can quickly indicate the location and type of the failure.

Appendix 1 – Typical physiological parameters monitored in anaesthesia and intensive care

A. Measured parameters

- Heart rate
- ECG
- Systolic, diastolic, and mean arterial pressure
- Pulmonary artery pressure (systolic, diastolic, and mean)
- Pulmonary capillary wedge pressure
- Central venous pressure
- Cardiac output

- Inspired O_2 fraction
- End-tidal CO_2 fraction
- Concentrations of volatile anaesthetics

- Arterial O_2 tension
- Arterial O_2 saturation
- Arterial O_2 content
- Mixed venous O_2 tension
- Mixed venous O_2 saturation
- Mixed venous O_2 content
- Arterial CO_2 tension
- Arterial pH

- Respiratory rate
- Tidal volume
- Minute ventilation
- Airway pressure (peak, mean, and end-expiratory)

- O_2 consumption
- CO_2 production

- Central temperature
- Peripheral temperature

- Urinary output

- Muscle relaxation

- EEG
- Evoked potentials.

B. Derived parameters

- Body surface area

- Stroke volume
- Cardiac index
- Stroke index
- Right ventricular stroke work (index)
- Left ventricular stroke work (index)
- Systemic vascular resistance
- Pulmonary vascular resistance

- Arterio-venous O_2 content difference
- O_2 extraction rate
- O_2 delivery
- O_2 consumption
- Alveolar-arterial O_2 gradient
- Venous admixture

- Dead space
- Alveolar ventilation
- Lung-thorax compliance
- Airway resistance

- Energy expenditure
- Respiratory exchange ratio
- Nitrogen balance.