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A data model for intensive care

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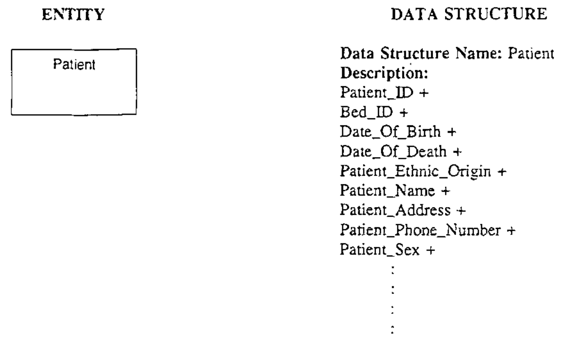
Abstract

The paper describes a model of clinical management data in a typical general intensive care unit, intended as a generic database specification for advanced intensive care computer systems. The data model was developed as part of the INFORM project. The INFORM project is summarised and the relevance of the data model to the objectives of the project are discussed. An object oriented extension to the entity relationship diagram methodology is presented. The methodology is illustrated with reference to some specific aspects of the data model including: the principle clinical entities; classification of patient state related data and the homogeneous patient group system. It is suggested that such a model will contribute to the better understanding of the data in the system, to the better design of future intensive care computer systems and to the setting of standards for medical data.

Introduction

This paper describes a model of clinical and management data in a typical general intensive care unit intended as a generic database specification for advanced intensive care computer systems. This data model was developed as part of 'INFORM' whose long-term aim is to develop, implement and evaluate a new generation of computer system for intensive care and other high-dependency environments (HDE) such as coronary care units, burns units, operating and recovery rooms. The focus of the preliminary phase of INFORM was the development of a *specification of the information requirements* for intensive care and for *an integrated software architecture with decision support* [1, 2]. This has been achieved through the following activities:

- conceptual modelling of intensive care decision-making, tasks and data by process and data modelling [3]
- evaluation of existing HDE information systems [4]
- development of a software architecture for decision-support using knowledge-based systems (KBS) methodology [5]
- monitoring of leading-edge technological devel-



Data Structure Name: Patient
Description:
Patient_ID +
Bed_ID +
Date_Of_Birth +
Date_Of_Death +
Patient_Ethnic_Origin +
Patient_Name +
Patient_Address +
Patient_Phone_Number +
Patient_Sex +
:
:
:
:

Fig. 1. Notation for entities and data structures. Part of the data dictionary entry defining the data structure for the 'Patient' entity is shown on the right.

opments, including networking, databases, human-computer interfaces, knowledge-based systems and monitoring instrumentation.

The data model has a number of purposes. It began as part of a systems analysis of the data arising in intensive care – from demographic to clinical to financial – and how the data are used in various tasks. This was done in conjunction with the process modelling during the conceptual modelling activity [3]. However, the model's main purpose is a formal specification of database requirements for a computer system. Finally, it is intended that the data model can contribute to the evolution of standards for medical record structures.

Matching the data model to the objectives of the INFORM system

The main objectives of INFORM are to improve the quality, efficiency and cost-effectiveness of patient care in the ICU. Quality of care is evaluated in terms of the outcome (particularly survival and quality of life) of the care process. Efficiency is defined as achieving a certain quality of care in a way which minimises use of resources; it is not concerned with optimising the quality of care. Cost-effectiveness is a measure of value for money of medical care; it is a balance between quality of care (outcome) and its total cost. There are thus 3 main subjects about which the system will require information: clinical patient data (monitoring, treatment, investigation, imaging); operational ICU management data (staffing, resources, costs); strategic data concerning quality of care, effectiveness, etc. Supporting these are various sets of reference data, for example standard protocols, drug information, reference ranges for monitored variables and itemised costing data.

Underlying INFORM is a hypothesis that a major contribution to improvement in quality of care can be made with the use of decision-support systems for intelligent monitoring, alarming, therapy advice, etc.. As a consequence, data (abstractions, filtered data, inferences, etc.) generated by decision-support should form part of the database and have been modelled in the appropriate sections of the data model.

The INFORM project was collaborative in nature, involving a large multi-national team. Furthermore, the data requirements of information systems for the intensive care environment are numerous and complex. It was recognised, therefore, that the most effective way of ensuring consistency throughout the development of the data model was by means of a formal data modelling methodology supported by software tools. The database structure which has resulted – while it is in many respects what one would have arrived at without such a methodology – has counter-intuitive features. For these reasons we would advocate the use of formal data analysis techniques, irrespective of the size or complexity of the data requirements, since such methodologies not only contribute to project management but the efficiency of the database. The aspects of the data model described here are those which illustrate the methodology and summarise the model best. It is presented in entirety in [6].

Methodology

The methodology is based on entity-relationship diagrams [7, 8], where entity represents a class of object, concept or event. Medical examples are 'Patient' (Fig.1), 'Diagnosis' and 'Treatment'. Each entity contains one or more data elements and may depend upon other entities through relationships. The graphical notation used is shown in Fig. 2.

The data dictionary is a database of all the components (including entities, structures and elements) of a model, whether these components appear in the diagram or not. The dictionary definition of an entity is known as a data structure, which refers to the organisation of the components (data elements and sub-entities) of that entity (e.g. the data structure for 'Patient' in Fig. 1). The syntax used for data structure definitions in this paper is as follows:

+ means AND
{} means ITERATIONS-OF the components enclosed
** means that text between the asterisks is a comment
() means that the enclosed component is optional

Each component of an entity (data element or sub-entity) should itself be defined. This process is repeated until all components of the model are defined in terms of data elements, which correspond to a simple item of data. Each data element has a number of defining attributes which include, at the very least, a description. The methodology permits the attributes to be set for specific parts of a model. For example, for physical measurements the attribute set includes units and reference range.

A natural way of modelling systems is with taxonomies or classification structures. It is possible to achieve this by extending the constructs of entity-relationship diagrams as follows. The solid circle annotating the 'Treatment' entity in Fig. 3 shows that it has sub-entities which are represented in a child diagram. The convention adopted here is that all elements in an entity are inherited by each sub-entity. The dictionary entries for each entity show only the elements at that level and not those inherited from the parent entity. Thus, sub-entity 'Medication' in Fig. 3 has the following total structure:

Patient_ID + Treatment_ID +
(Care_Plan_ID) +
Date_Time_Prescribed + HCP_ID +
Date_Time_Cancelled + HCP_ID +
Drug + Dose_Prescribed +
Administration_Route +
{Time_To_Be_Given} + ...

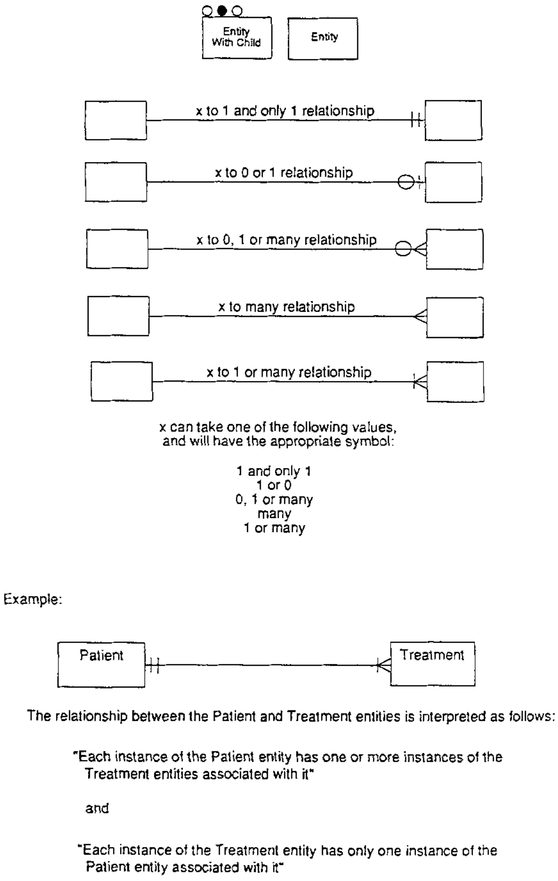
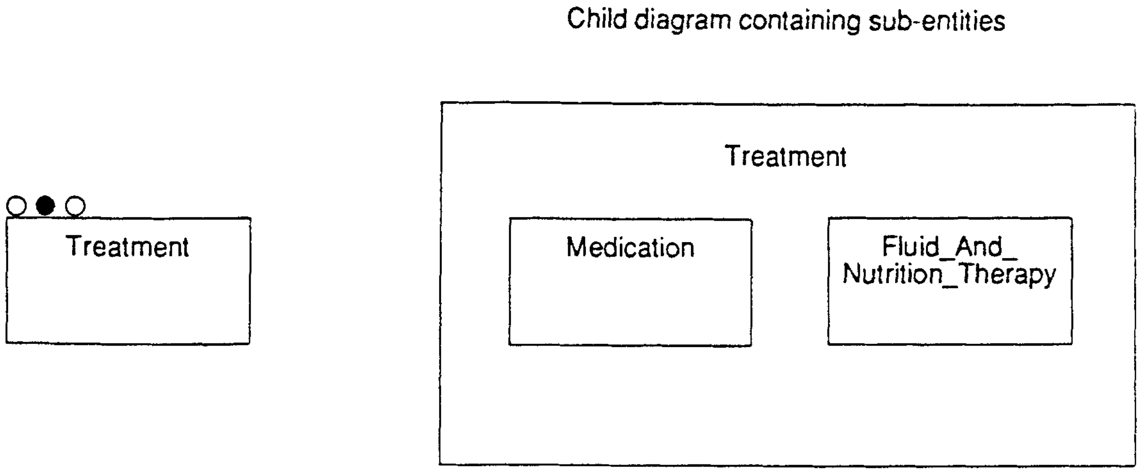

Entity With Child
Entity
x to 1 and only 1 relationship
x to 0 or 1 relationship
x to 0, 1 or many relationship
x to many relationship
x to 1 or many relationship
x can take one of the following values, and will have the appropriate symbol:
1 and only 1
1 or 0
0, 1 or many
many
1 or many
Example:
Patient
Treatment
The relationship between the Patient and Treatment entities is interpreted as follows:
"Each instance of the Patient entity has one or more instances of the Treatment entities associated with it"
and
"Each instance of the Treatment entity has only one instance of the Patient entity associated with it"

Fig. 2. Graphical notation for data modelling.

and 'Fluid_And_Nutrition_Therapy' has the structure:

Patient_ID + Treatment_ID +
(Care_Plan_ID) +
Date_Time_Prescribed + HCP_ID +
Date_Time_Cancelled + HCP_ID +
Fluid + Volume_Prescribed +
Infusion_Rate + Batch_Number +
{Drug_Added + Drug_Quantity} + ...

This object-oriented approach [9] provides an expressive and compact form of modelling. In developing the model, entities were examined for common data elements and, where found, the possibil-



Dictionary entries corresponding to symbols above:

Data Structure Name: Treatment
Description:
Patient_ID +
Treatment_ID +
(Care_Plan_ID) +
Date_Time_Prescribed +
HCP_ID + * ID of person prescribing *
Date_Time_Cancelled +
HCP_ID * ID of person cancelling prescription *

Data Structure Name: Medication
Description:
Drug +
Dose_Prescribed +
Administration_Route +
{Time_To_Be_Given} +
:
:
:

Data Structure Name: Fluid_And_Nutrition_Therapy
Description:
Fluid +
Volume_Prescribed +
Infusion_Rate +
Batch_Number +
{Drug_Added + Drug_Quantity} +
:
:
:

Fig. 3. Classification structures: entity – sub-entity relationships. The solid circle above the 'Treatment' entity (top left) shows that it has a child diagram (top right). The data structure definitions for 'Treatment' and its sub-entities are shown below.

ity of creating a classification structure was considered. The rule was applied that each entity (object) should have at least one data element [9].

When a model is being developed as a design for a relational database [8] each entity corresponds to a simple table (or file) which does not permit repeating elements (fields). Repeating elements are eliminated in a process of normalisation which typically results in one additional table per group of repeating elements. As this is a generic model, no decision has been made as to how the database is to be implemented and thus repeating elements and other structures using the above notation have been permitted.

The initial choice of entities was based on the original organisation of information on paper forms. Some of the resulting entities were: ICU chart, treatment, patient information, therapeutic drug monitoring, blood transfusion, chemistry investigation, haematology investigation, histopathology investigation, imaging, microbiology investigation, neurological observations and peak flow monitoring.

Software

The modelling methodology and diagramming notation described here has been applied using a PC-based CASE tool, System Architect (Trade Mark, Popkin Software). All entity-relationship diagrams and the data dictionary have been created and modified using System Architect.

The primary clinical entities

As will be seen later, the data model contains a large number of entities. However, most of the patient clinical data fall into a few entities (Fig. 4): 'Imaging', 'Lab_Investigation', 'Treatment' and 'Clinical_Measurement'. Each of these relates uniquely to one 'Patient' and is initiated by one 'Health_Care_Professional'.

The data analysis procedure described above was carried out using the entities derived from the paper forms as a starting point. When ordering or reporting the results of any of chemistry, haematology, histopathology or microbiology investigations or therapeutic drug monitoring, the type of data which has to be specified is similar. Although these investigations may be carried out in different locations and the data content of the forms differs; their data structure is common as shown in the 'Lab_Investigation' entity:

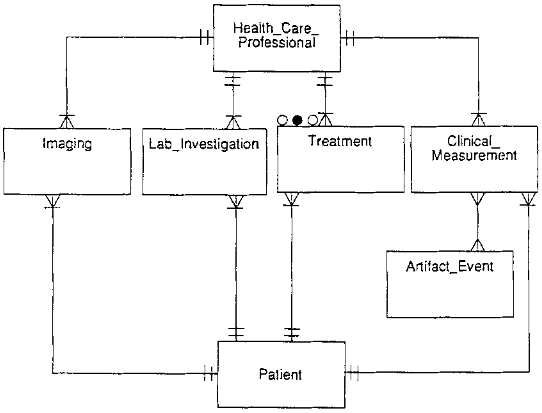


Fig. 4. The primary clinical entities.

Patient_ID + HCP_ID +
(Care_Plan_ID) +
Specimen_Type + Specimen_
Site + {Date_Time_Sample} +
Date_Time_Investigation_Requested +
Lab_Data +
{Test_Request + {Date_Time +
Test_Result}} + Lab_Report

A particular sample may have more than one test associated with it and therefore more than one result.

It can be seen that Imaging (Fig.4) is a separate entity from 'Lab_Investigation' since the elements 'Specimen_Type' and 'Date_Time_Sample' are irrelevant in this context. In addition an imaging request has a set of details, (e.g. 'Where_Imaging_To_Take_Place'), which are specific to imaging and not part of the request for other types of investigation. Hence a separate entity has been assigned to imaging.

All treatments happen to a patient, are ordered or initiated by a 'Health_Care_Professional' (HCP) at a particular time and are subject to cancellation by an HCP. This part of the 'Treatment' data structure (Fig. 3) applies whatever the treatment. There are many types of treatment that are documented in records of patient care and whose data structure depends on the treatment type.

Some treatments have explicit orders and records of administration (e.g. medication, fluid therapy, nutrition therapy, blood products, surgical procedures, etc.). For some treatments the ‘order’ may comprise nothing more than an indication of the start of a particular type of treatment at a particular time. Details relating to ventilator therapy (e.g. dial settings) may in some cases be an order or in other cases be part of the record of that treatment. The challenge in data modelling is to identify the most effective set of entities to reflect this complexity and yet be usable. This was done by looking for common data elements among the types of treatment documented on the paper forms. As an example, consider two of the resultant entities, ‘Medication’ and ‘Fluid_And_Nutrition_Therapy’ (Fig.3). The main difference between these two entities is that treatments covered by ‘Medication’ are administered at distinct time points whereas ‘Fluid_And_Nutrition_Therapy’ is continuous. The structure (Fig.3) allows for a series of individual medications to be planned (depending on whether one or more ‘Medication_Times_To_Be_Given’ are specified). Each value of ‘Medication_Time_To_Be_Given’ should correspond to a record of medication administration:

Medication_Date_Time +
Medication_Dose_Given +
(M_Cumulative_Dose_Given) + HCP_ID.

This ‘Medication’ entity covers regular (periodic) medications, as required (on-demand) medications, and once only, premedication or variable dose drugs where the time to be given and the actual time given are each recorded once.

The ‘Fluid_And_Nutrition_Therapy’ entity covers IV therapy and parenteral nutrition therapy. Here a basic fluid is prescribed which may have any optional number of added quantities of drugs, electrolytes and/or vitamins. Unlike the ‘Medication’ entity, the ‘Fluid_And_Nutrition_Therapy’ entity allows for several records of administration of a particular therapy administration. The other treatment entities are: nursing; surgical procedure; blood product; dialysis and filtration; haemoperfusion; defibrillation; pacemaker; intra-aortic balloon pump; ventilator; oxygen; continuous positive airway pressure; ECMO.

‘‘Clinical_Measurement’ is an order-result entity for automatic and manual bedside measurements and observations, including monitoring. It has the following data structure:

⋆ Request ⋆
Patient_ID + HCP_ID +
(Care_Plan_ID) +
Date_Time_CM_Requested +
Variable_ID + Collection_Method +
(On_Line_Port) +
⋆ needed if Collection_Method Automatic ⋆
Derivation_Method + Initial_Measurement_Time + Sampling_Interval +
Database_Storage_Interval +
High_Limit_Alarm + Low_Limit_Alarm + High_Trend_Alarm + Low_Trend_Alarm +
⋆ Actual Data ⋆
{Date_Time + Value} +
{Date_Time + Limit_Alarm_State +
Trend_Alarm_State} +
{Date_Time + Systematically_Pre_Processed} +
{Date_Time + Cleaned_Up_Value} +
{Date_Time + Symbolized_Value}

Although based originally on an analysis of current manual practices and computer-based systems, this data structure is a design for an advanced ICU system. The first section is the measurement request or detailed plan and the second section contains the results. ‘Patient_ID’ and ‘HCP_ID’ identify the patient and the health care professional (HCP) planning the measurement. ‘Care_Plan_ID’ is an optional pointer to the ‘Care_Plan’. ‘Variable_ID’ identifies the variable to be measured, full details of which are in the reference data model, including physiological classification (see below). The ‘Collection_Method’ may be manual, derived or automatic. In the latter case, the ‘On_Line_Port’ may be recorded. For derived variables, ‘Derivation_Method’ contains the derivation formula or a pointer to it.

‘Date_Time_CM_Requested’ refers to the

date and time at which the HCP has made the request. 'Initial_Measurement_Time' allows measurements to be synchronised (e.g., fluid balance to be started from 00.00hr). 'Sampling_Interval' is the interval at which the variable is to be sampled from the monitor, computed or the user prompted for manual measurement. 'Database_Storage_Interval' refers to the interval at which the value of the variable is to be entered into the database. The final section of the request allows limit and trend alarms to be set. It is expected that limit alarm settings would usually be obtained from the monitor (assuming that the computer system is separate from the bedside monitor).

The time series data for the variable are described in the repeating structure: {Date_Time + Value}. A similar structure follows for the limit and trend alarm. This repeats every time an alarm is fired or cancelled (i.e. when the alarm state changes).

The final 3 structures of the 'Clinical_Measurement' entity are exploratory and are to be derived from the decision-support sub-system. 'Systematically_Pre_Processed' refers to data that have undergone digital signal processing. Different filters, line fitting, power spectrum estimation, descriptive signal statistics are some methods that may be used. The 'Cleaned_Up_Value' is a filtered version of the 'Systematically_Pre_Processed' data with artifacts removed. 'Symbolized_Value' is a qualitative abstraction such as high, normal or low; or rising, steady or falling (an indication of linear trend) to be used for automated physiological assessment.

Measurements may be confounded by artifacts such as line flushing, electrical problems and patient movement. Thus each 'Clinical_Measurement' may be related to several 'Artifact_Event' entities (Fig. 4).

As discussed above, the 'Treatment' entity (and sub-entities) holds detailed data relating to a specific treatment order and record. At a higher level an individual treatment may be carried out as part of a care plan for the patient (Fig. 8). The care plan will identify problems, set clinical goals and decide a plan for treatment, monitoring and investigation. It will be based on assessments of physiological and psychosocial state and may be derived from standardised protocols or guidelines for acceptable care.

Classification of patient state related data

Patient state related data are obtained as a result of clinical measurement, laboratory investigation or imaging (Fig. 4). In the data model each state related variable is identified by the element 'Variable_ID', which has been classified in the reference data model according to the method of acquisition (Fig. 5) and the physiological system to which it relates (Fig. 6). Figures 5 and 6 show only the classes with which the variables may be associated and not the variables themselves. (The directed acyclic graph which results when each variable is shown in all the classes to which it belongs is too large to be shown.) These graphs (or 'tangled hierarchies') for the reference data model were developed using KEE (Trade Mark, Intellicorp Inc.) and the resultant classifications of the variables entered into the System Architect data dictionary.

Each variable can be acquired in one or more ways. The data dictionary reference data model for 'Variable_ID' includes an 'Acquisition' attribute which contains the relevant categories in the taxonomy of Fig. 5. For example, urine output is classified under OUTPUT.COLLECTION (which is manual), URINE.MONITOR (automatic) and INFORM.SYSTEM.DERIVED. The latter is used for urine output computed over a period (e.g. 24 hours). For all variables that can be calculated indirectly, the possible derivation functions are also held in the reference model. Whether the variable values are to be system derived or input directly in each particular case is determined in the clinical measurement 'request'.

The physiological classification (Fig. 6) is a way of grouping together related variables in a functional sense. Again, each 'Variable_ID' may be multiply classified. For example, urine output is classified under WATER.METABOLISM and RENAL.SYSTEM, and serum bilirubin is classified under HAEMOPOIETIC.SYSTEM and GASTROINTESTINAL.SYSTEM. Some classes

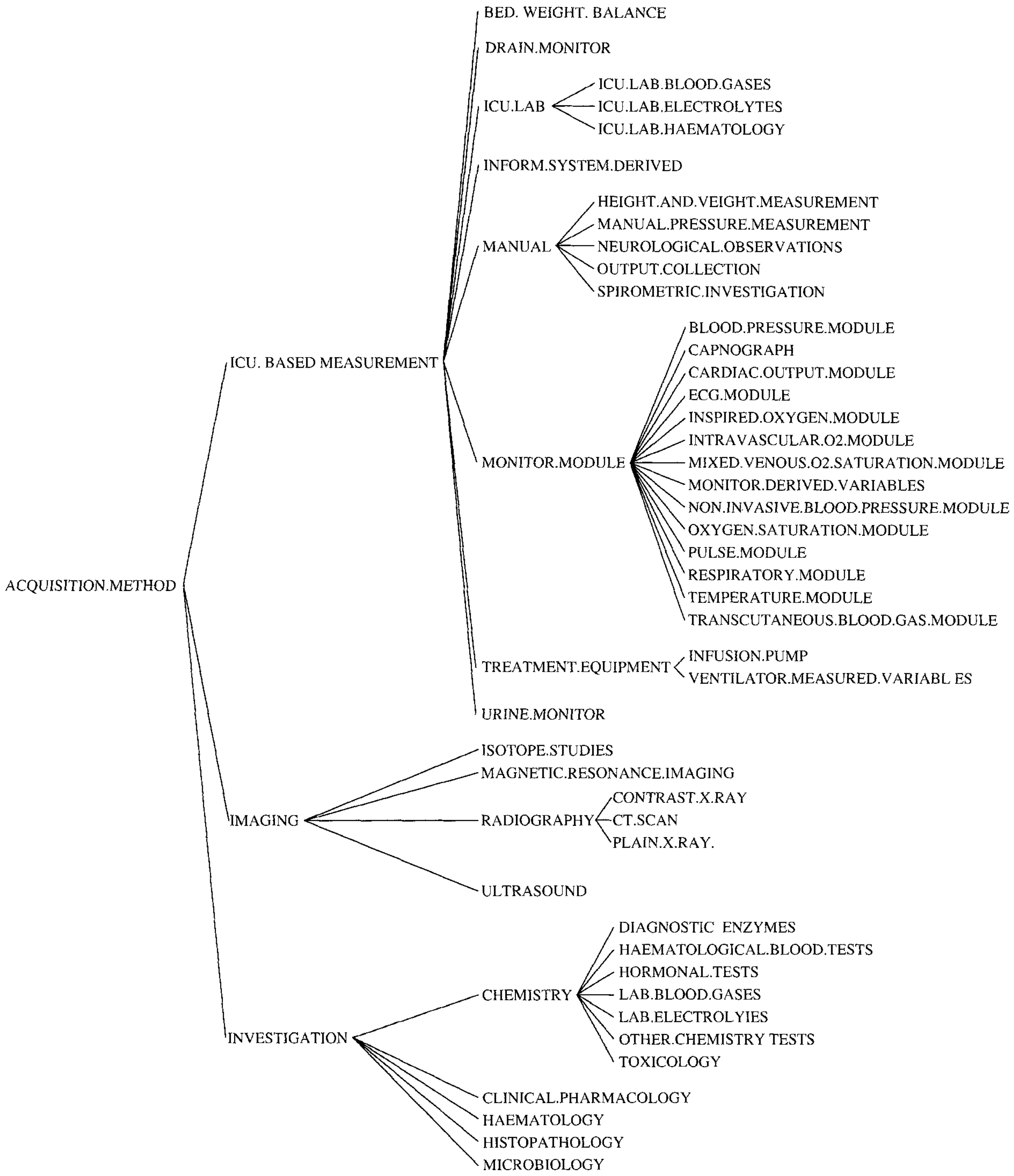


Fig. 5. Classification structure for patient state related data based on method of acquisition.

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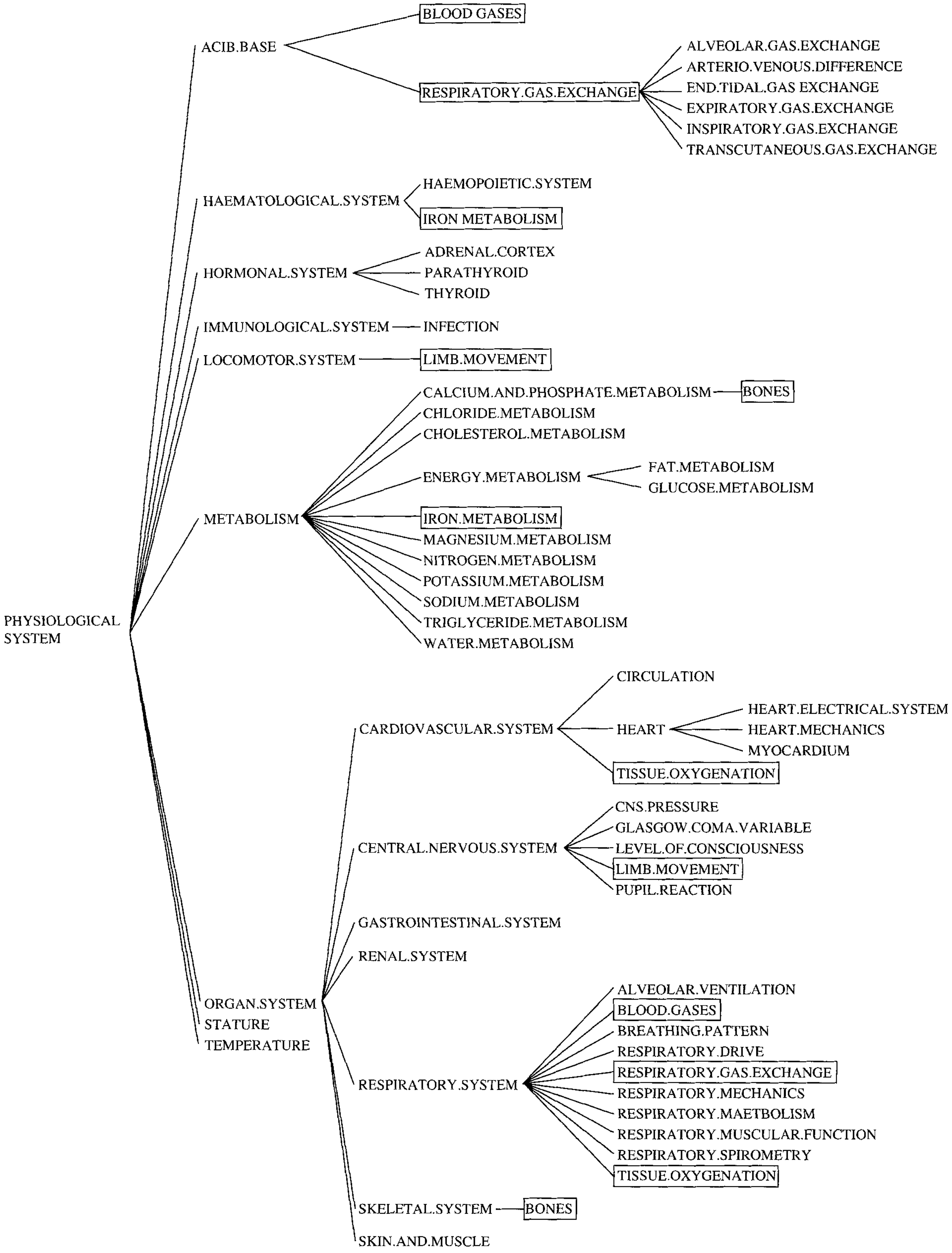
Fig. 6. Classification structure for patient state related data based on physiological systems. The box around a class indicates that it is multiply classified.


PHYSIOLOGICAL SYSTEM
ACIB.BASE
BLOOD GASES
RESPIRATORY.GAS.EXCHANGE
ALVEOLAR.GAS.EXCHANGE
ARTERIO.VENOUS.DIFFERENCE
END.TIDAL.GAS EXCHANGE
EXPIRATORY.GAS.EXCHANGE
INSPIRATORY.GAS.EXCHANGE
TRANSCUTANEOUS.GAS.EXCHANGE
HAEMATOLOGICAL.SYSTEM
HAEMOPOIETIC.SYSTEM
IRON METABOLISM
HORMONAL.SYSTEM
ADRENAL.CORTEX
PARATHYROID
THYROID
IMMUNOLOGICAL.SYSTEM
INFECTION
LOCOMOTOR.SYSTEM
LIMB.MOVEMENT
METABOLISM
CALCIUM.AND.PHOSPHATE.METABOLISM
BONES
CHLORIDE.METABOLISM
CHOLESTEROL.METABOLISM
ENERGY.METABOLISM
FAT.METABOLISM
GLUCOSE.METABOLISM
IRON.METABOLISM
MAGNESIUM.METABOLISM
NITROGEN.METABOLISM
POTASSIUM.METABOLISM
SODIUM.METABOLISM
TRIGLYCERIDE.METABOLISM
WATER.METABOLISM
ORGAN.SYSTEM
CARDIOVASCULAR.SYSTEM
CIRCULATION
HEART
HEART.ELECTRICAL.SYSTEM
HEART.MECHANICS
MYOCARDIUM
TISSUE.OXYGENATION
CENTRAL.NERVOUS.SYSTEM
CNS.PRESSURE
GLASGOW.COMA.VARIABLE
LEVEL.OF.CONSCIOUSNESS
LIMB.MOVEMENT
PUPIL.REACTION
GASTROINTESTINAL.SYSTEM
RENAL.SYSTEM
RESPIRATORY.SYSTEM
ALVEOLAR.VENTILATION
BLOOD.GASES
BREATHING.PATTERN
RESPIRATORY.DRIVE
RESPIRATORY.GAS.EXCHANGE
RESPIRATORY.MECHANICS
RESPIRATORY.MAETBOLISM
RESPIRATORY.MUSCULAR.FUNCTION
RESPIRATORY.SPIROMETRY
TISSUE.OXYGENATION
SKELETAL.SYSTEM
BONES
SKIN.AND.MUSCLE
STATURE
TEMPERATURE

```
Data Structure Name: HPG_Classification
        Description:
                Patient_ID +
                Date_Time +
                HPG_ID


Data Structure Name: HPG_Variable
        Description:
                HPG_Variable_ID +
                HPG_ID
                HPG_Variable_Standard_Mean +
                HPG_Variable_Standard_Variance +
                HPG_Variable_Standard_Distribution +
                HPG_Variable_Actual_Mean +
                HPG_Variable_Actual_Variance +
                HPG_Variable_Actual_Distribution


Data Structure Name: Homogeneous_Patient_Group
        Description:
                ICU_ID +
                HPG_ID +
                HPG_Based_Protocol +
                HPG_Mean_Level_Resource_Adequacy +
        * classifying elements *
                HPG_Diagnosis +
                HPG_Level_Of_Severity +
        * cases *
                HPG_Number_Of_Patients +
                HPG_Number_Of_Deaths
```

Fig. 7. Data structures for the 'HPG-Classification', 'HPG-Variable' and 'Homogeneous-Patient-Group'. The classifying elements for the 'Homogeneous-Patient-Group' are those used in preliminary testing of the methodology (see text).

may themselves be multiply classified. For example, BLOOD.GASES are classified under ACID BASE and RESPIRATORY.SYSTEM. This classification system can be used as reference information called upon by generic processes for grouping together data for display purposes, for summary reports, for organ- system specific reports etc. and also for generating series of menus for selecting variables for monitoring or display.

In an implementation, it should be possible to classify new variables within the functional classification and to introduce new functional groupings if necessary. The aim is a flexible system which can respond to the needs of medical innovation and research.

Care evaluation, cost-effectiveness and planning

The following describes a methodology for patient classification that has been developed to allow cost-effectiveness assessments of ICU care to be made. Each patient is grouped into an 'HPG__Classification' (Figs. 7 and 8), where HPG is a 'Homogeneous__Patient__Group' that refers to patients with the same diagnostic code and disease severity. The 'Homogeneous__Patient__Group' entity contains classifying information for an HPG and descriptive statistics relating to the patients who have been classified as belonging to that HPG. In preliminary testing, a diagnostic code and APACHE II disease severity score [10] have been used as classifying factors (Fig. 7). Associated with each HPG are the statistics of many output 'HPG__Variable' such as survival, length of stay and costs. Each 'HPG__Variable' entity contains a variable relating to a particular HPG together with the mean, variance and distribution of the variable for patients in the ICU concerned, and standard values of these parameters to which the ICU is being compared (Fig. 7). Such a concept will provide a basis for inter-unit comparisons, over comparable patient populations, of cost-effectiveness, outcome and quality of care and also for setting norms or goals for units to achieve. It should be stressed again that patients are grouped by disease and severity, and not by the dependent HPG__Variables. Other strategic issues associated with the ICU are 'Policy', 'ICU__Performance' and 'ICU__Investment__Programme'.

The paper has thus far shown only fragments of the model. The full entity-relationship diagram is shown in Fig. 8.

Conclusions

The paper has presented an overview of a data model for intensive care and the methodology used in its development. The main purpose of this model is to provide a formal statement of database requirements for advanced intensive care computer systems. However, it also stands in its own right as a systems analysis of data arising in a typical in-

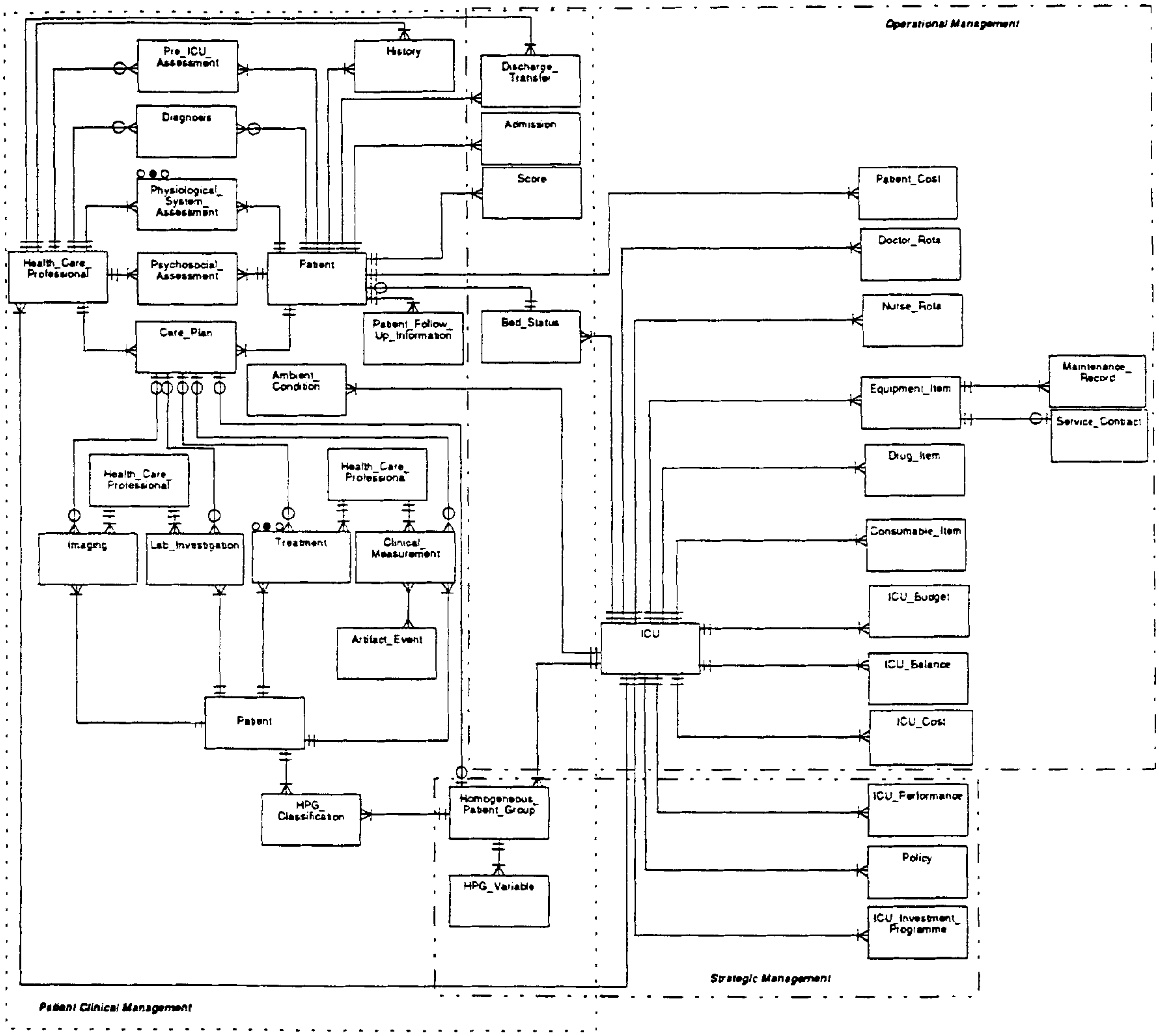


Fig. 8. The overall data model.

tensive care unit. It is hoped that the model will contribute to the better understanding of this data, to the better design of future intensive care computer systems and to the setting of standards for medical data [3, 11, 12].

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