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Modelling Health Care Processes for Eliciting User Requirements: A Way to Link a Quality Paradigm and Clinical Information System Design

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Abstract. Hospital information systems have to support quality improvement objectives. The design issues of health care information system can be classified into three categories: 1) time-oriented and event-labelled storage of patient data; 2) contextual support of decision-making; 3) capabilities for modular upgrading. The elicitation of the requirements has to meet users' needs in relation to both the quality (efficacy, safety) and the monitoring of all health care activities (traceability). Information analysts need methods to conceptualise clinical information systems that provide actors with individual benefits and guide behavioural changes. A methodology is proposed to elicit and structure users' requirements using a process-oriented analysis, and it is applied to the field of blood transfusion. An object-oriented data model of a process has been defined in order to identify its main components : activity, sub-process, resources, constrains, guidelines, parameters and indicators. Although some aspects of activity, such as "where", "what else", and "why" are poorly represented by the data model alone, this method of requirement elicitation fits the dynamic of data input for the process to be traced. A hierarchical representation of hospital activities has to be found for this approach to be generalised within the organisation, for the processes to be interrelated, and for their characteristics to be shared.

1. Introduction

The initial aim in the development of DRG-based and outcomes-oriented evaluation programs was to increase control over the economic consequences of health care practices. Nowadays the continuous improvement of quality of care, and the accreditation of health care activities, are two predominant objectives in our health care systems. Furthermore, in several countries, the concept of sanitary safety and the rules of sanitary control have been defined by law, in order to reduce the occurrence of risky situations in the areas of therapy, diagnosis and prevention. This mandatory context prompts hospitals to federate resources, to define methodologies, and to build tools in order to set up a real-time risk and vigilance management system closely related to the clinical information management system.
A healthcare quality paradigm requires not only the measurement of the outcomes of processes of care, but also the description and the assessment of the ways used to perform activities throughout each identified process. The need for subsequent improvements in health care delivery stresses the need for a continuous traceability of all care activities, the reduction of variations in practices, and the detection, measurement and prevention of adverse events occurring during health care delivery [1].
The primary objective of a clinical information system is to trace care activities, and to document all the events of the care processes. It requires the identification and the description of the sequence of the elements of the process [2]. Thus the demands for patient-centred and integrated clinical data repositories have shifted towards process-oriented clinical information systems. As a result, the design of hospital information systems is changing from a retrospective and specific data-collection approach to a prospective and multipurpose one [3]. Departing from their role as static repositories of data, information systems must now fit the dynamics of clinical pathways [4]. The use of

anonymous and encoded datasets for discharge summaries is being replaced by the daily usage of narrative data, to reinforce patient care by physicians and nurses, and in accordance with mandatory requirements of vigilance. These factors are considered as the foundation for the gathering and long-term storage of clinical data into appropriate and structured electronic medical records. There are two reasons for this: to supply quality improvement programs with reliable and real-time indicators, and to provide professionals with relevant decision support.
It is now well established that for quality measurement to be practical, relevant and not time consuming, it must be integrated into the routine provision of care and, whenever possible, use information systems [5]. As regards the integration of the quality paradigm into a clinical information system, design issues remain, and can be classified into three categories : 1) time-oriented and event-labelled gathering and retrieval of data; 2) support of decision-making and real-time transverse process assessments; 3) capability of the system to be upgraded in a modular way by simple addition of new processes and new indicators. One can consider that a wide variety of applications in a hospital deal with the manipulation and the representation of collections of activities. Designing and assessing the performance of all patient-centred activities requires information to be shared among these applications, and also requires three characteristics of the context of healthcare information management to be integrated [6]: large-scale collaborative and multi-user activities, event-oriented data gathering, and shared quality objectives.

2. Objectives

The design of a clinical information system should build on the work of quality workgroups in order to provide users with a consensual way to trace their activities, and a convenient support for decision-making [7,8]. Hierarchical and structured design techniques, such as SADT or IDEF0 [9,10], have been used to describe activities and data within large and complex systems. The purpose of this paper is to apply the concept of enterprise business processing to: 1) analysing patterns of care activities, 2) building a systemic view of patient-centred processes; and 3) improving our knowledge and understanding of hospital organisation. The underlying objective is to find a method of establishing a link between a quality paradigm and a clinical information system, in order to improve the elicitation of users' requirements. A description of the hospital blood transfusion process is used as basic example to specify a model of process representation. This model is then applied to identifying and structuring the main user requirements in a computerised clinical information system. These requirements are expressed as roles to be defined, functions to be implemented and data to be computed.

3. Methods

A process is a structured collection of activities, a set of partially ordered steps intended to reach a goal [11]. Processes can produce objects or define organisational responses to some situations, define how goals are to be reached, or how they are to be maintained. A process model is an abstract description of an actual or proposed process. The basic process model identifies: 1) agent - an actor (human or machine) who performs a process element; 2) role - a coherent set of process elements to be assigned to an agent as a unit of functional responsibility; 3) artefact - a product created or modified by the enactment of a process element. According to the level of granularity, some process elements can be viewed as sub-processes. Various kinds of processes can be identified within an enterprise [11]: individual human work processes, organisationally-defined processes, operational processes, production processes, management and change processes, etc. In the context of clinical activities, the main types of processes encountered are individual processes (e.g. therapeutic ordering processes and, broadly speaking, decision-making processes), and organisational or logistic processes (e.g. patient registration, blood sample transportation, appointment records, etc.). Processes and their related set of activities can be considered as scenarios according to which a user interacts with its environment (other users, patients, context of practice), has a set of responsibilities and reaches goals. The methodology we followed consisted of two steps, from process modelling to the definition of requirements of the information system. The first step was to extract and structure the description of activities in order to know what is going to be done, who is going to do it, when and where it will be done, how and why it will be done, and who is dependent on its being done. This

step was performed by the workgroups involved in the medical transfusion quality assurance program, by means of semi-structured questionnaires [12] (table I). The quality material to be analysed consists of : 1) a set of chronological steps describing care actions; 2) a set of activities by actor and by step; 3) a set of data to be retrieved in the history of the patient and to be delivered to the actor; 4) a set of parameters to be fed in at each step; 5) a set of advice to be sent to an actor; 6) a set of data / documents to be transmitted in order to chain two activities, with their modality of communication (manual-driven, automatic event-driven); and 7) a set of indicators by activity, computed by means of parameters, with rules of computing and interpreting. The second step was the translation of this description into data types, related values, user types and utilisation profiles.

Table 1. Structured analysis of the documents : definition of the objects and for some objects definition of their attributes and methods (adapted from [12])

Questions	**Objects**	**Examples**
What documents are used in the system ?	document	questionnaires, instructions, reports, intermediate products, reference manuals
Who / what gets the document ?	receiver	client, staff, department, external organisation
Who / what makes the document ?	creator	employees, external staff, equipment
What resources are used to make the document ?	resource	reference manuals, clinical exam
What events cause the document to be made ?	event	arrival of an invoice, order entry

Questions	**Characteristics**
What are the specific fields of the document ?	attributes
What are the basic elements of the document ?	attributes
What does the maker or the acceptor do with items in document ?	methods
How does the resource or the event to make the document ?	methods
What does the acceptor do to accept the document ?	methods
What does the maker do to provide the document ?	methods

4. Results

From a top-level point of view, the data model of a process can be abstracted into a model with two main elements (figure 1): 1) a step element which is related to the components of an activity according to the ICOM model of SADT/IDEF0 actigram: input, rules or controls, resources (material, person) and output; 2) a data element which is related to a set of metadata used to describe the step element and its related indicators. As shown in figure 2, the blood transfusion process is a sequence of six main components or sub-processes starting with the physician's prescription, ending with the reporting of the monitoring of the perfusion of blood unit(s) to a patient. The input of the overall process is a patient to be transfused and the output is the transfused patient. The elicitation of the requirements of the blood transfusion information sub-system has been performed according to the following rules: 1) the categories of users are issued from the actors of the process; 2) the name of users' functions is the name of each element of the process (activity or sub-process); 3) the resource documents have been split into data units in order to outline the resource materials and their attributes.

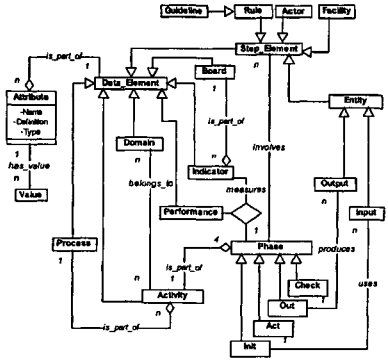


Figure 1. Object diagram of a process data model (UML notation)

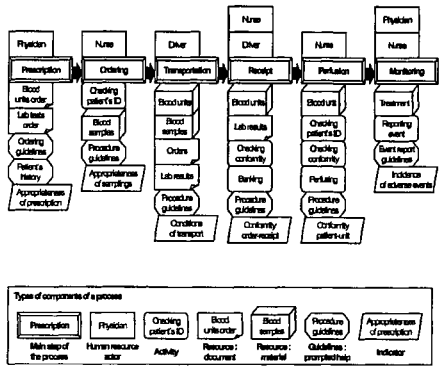
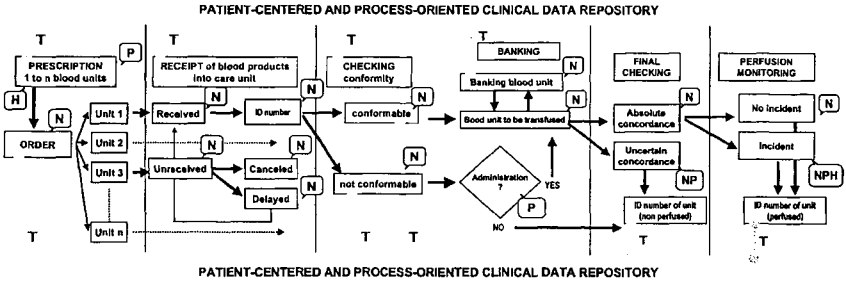


Figure 2. The blood transfusion process, showing the main steps and their components

Data flows have been deduced from the sequencing of the main steps of the process. The data that are concerned with the traceability of the transfusion process can be grouped according to eight domains: 1) socio-demographic data of the patient; 2) history of blood transfusions updated after each new perfusion; 3) clinical and biological conditions of the patient; 4) set of the prescriptions with their reasons; 5) follow-up of orders (unsent, completed); 6) data related to the checking of the conformity between each delivered blood unit and the blood group of the patient; 7) data related to the perfusion and the monitoring of each blood unit; 8) data related to the reporting of an adverse event during or after blood transfusion. Data have also been deduced from the indicators defined to assess the appropriateness of each order of blood transfusion.



ID: Identification - N: Nurse - P: Physician - H: Hemovigilance Department - T: Element to be stored for the process to be traced

Figure 3. Dataflow diagram of the blood transfusion process, and the background of the traceability of the process into the patient-centered clinical data repository

Figure 3 shows the workflow diagram with the key data to be traced into a patient record. Additional details depict the relationships between actors and their responsibilities in the process. The attributes of a prescription have been defined, with their related set of values, the details of which contain: 1) the items for the traceability to be relevant : identity of the physician, input time; 2) the items for process conformity assessment: type of product, reasons for order, scheduling. Different contexts of blood transfusion have been described, and allow the refinement of some of the previous characteristics (normal condition of transfusion, vital emergency). For each type of user, a set of functions has been deduced from the involvement of actors within the process. According to the design of the blood process, the physician's functions consist of: 1) a set of options related to the blood prescription; 2) a set of options related to the lab test prescription; 3) options that display to a physician the overview of patient follow-up such as the current prescriptions, the status of each order (held, suspended, achieved, in process), the past history of the transfusion events, and the different lab test results.

5. Discussion

The methodology we adopted is based on the characterisation of a process data model in which users' requirements are elicited. The main background of this methodology is the involvement of the users in a way that meets not only their needs of available data but also their needs of means of communication. All cases are explored: existing work practices, ultimate work practices, and interim work practices [13]. This aspect is strongly related to the users' acceptance of the system, as it has been well established that user involvement has a significant impact on the quality of the resultant systems [14]. Thus, if some of the key factors of the development methodology are reusability and standardisation, the role of information analysts has to shift to a better understanding of the problems in practice. One of the conditions for the adoption and the use of methods and tools for the activities to be traced, is the analysis of the process and the capture of dependencies [15]. While some parts of the scenarios, such as "where", "what else" and "why", are poorly represented simply by the process data model, this approach suits the dynamics of data input. Within a hospital, the development of information systems and quality management programs must be viewed as a two-component strategy aimed at refocusing the staff perspective in the accomplishment of the organisation's goals [16]. Information system and quality management share a considerable degree of commonality in their end objectives [17]. Process-oriented analysis is of value in introducing a quality paradigm into the design of a clinical information system. This help us to satisfy four objectives: 1) systematic description of the activities; 2) elicitation of useful data to perform real-time trend charts; 3) supplying contextual on line help for decision-making; and 4) maintaining a continuous involvement of the actors.

Healthcare activities remain fundamentally human activities. Their improvement requires a better understanding of the co-ordination between actors; this could be achieved by analysing the scenarios and the data exchanged between actors during the processes. Their continuous assessment could benefit from process-oriented information systems used to structure patient-centered data repositories. A better understanding of an organisation and the measurement of its performance depend on the understanding of all its activities. Although hospital processes are complex and not very well known or categorised, the way to build a systemic view of hospital activities starts with the modelling of processes. Then an organisation ontology has to be found for the processes to be interrelated, and their characteristics to be shared [18]. In conclusion, we suggest that promoting quality assurance in the hospital sector could inherit from industrial models, validated in the field of production quality. But these models cannot be imported with success into an hospital without both a better understanding of roles and actors, and a hierarchical analysis of the objectives of the institution.

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