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A careflow management system for chronic patients

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Abstract

The management of chronic patients is a complex process, which requires the cooperation of all primary care professionals and their interaction with specialists, laboratories and personnel of different organizations. In this paper we show how a Careflow Management System (CfMS) may represent an essential component of an innovative Health Information System (HIS) able to handle the information and communication needs underlying chronic diseases management. On the basis of a general architecture designed for chronic diseases, we describe a CfMS implementation in the area of Diabetes management; such a system embeds EPR and telemedicine functionalities as end-users applications as well as a module for inter-organizational communication based on contracts and on XML messages.

Keywords:

Health informatics, chronic disease management, careflow management systems, inter-organizational communication

Introduction

The increase of life expectancy due to the improvements of the economical conditions and of the medical treatments in western countries has caused the population ageing and the increasing need of managing chronic diseases. The economical burden of such diseases is now staggering, and the overall structure of health care has been profoundly revised in the last few years. As a matter of fact, it has been recognized that the majority of chronic conditions, such as cardiovascular diseases, hypertension, diabetes and dementia can be managed within the primary care setting. Moreover, several stages of cancer can also be treated at home, too, and such treatments may become practical only through an involvement of primary care services. It must be noted that several pathologies are likely to co-occur in many patients, and in particular in older people. As a consequence, the patient should be treated following the so-called holistic approach. Within this approach we can find several models of primary care services, ranging from case management, intensive case management, Assertive Community Treatment and Community based practices [1,2,3]. A common characteristic of all those models is that several actors should strictly cooperate to treat patients: *General Practitioners (GPs)* should take care of managing the overall patient treatment and act as gatekeepers for granting access to hospital services, drugs delivery and laboratory exams; *Practice Nurses* should manage home care and patients' education; *Pharmacists* could help patients to understand the effect of their medicines, the practical aspects of their medications and the strategies to obtain the best drug effect; *Dietologists* should define with the patient diet plans and finally *Psychologists* and *Patients' Associations* should play the crucial role of improving patient's empowerment and self-management capabilities [4]. The management of the information flows between the different actors involved in those primary care services is therefore mandatory. Information and Communication Technology (ICT) is a natural solution for dealing with such problems. Several tools have been proposed to handle particular diseases, such as Diabetes [5], or particular case management processes, such as post-stroke patient rehabilitation [6].

The kind of ICT support to case management varies widely. The first attempts resorted to the use of fax and e-mails to ensure coordination and data transfer. More recently, the use of both groupware and careflow technology has been proposed [7]. Rather interestingly, even the use of case management software cannot be considered as sufficient to handle the complexity of primary care. As a matter of fact, all the actors involved in primary care need both to communicate between each other, and to communicate with clinical service providers. The patients often need to be visited by specialists and they must also perform laboratory tests and different kinds of instrumental exams, such as radiography, echography and so on. The definition of a technological infrastructure which enables inter- and intra-organizational communication advocates for the design of new strategies to properly manage communication, able to conjugate careflow systems for case management with wider systems for inter-organizational collaboration. This paper will describe a technological implementation in the area of Diabetes care, designed to explicitly handle the overall communication process underlying chronic disease management.

The clinical problem

Diabetes Mellitus, a major metabolic disease related with a reduced or impaired capability of the body to regulate the Blood Glucose Level, is now reaching epidemic proportion in western countries. The combination of population ageing, unhealthy diet, obesity and sedentary life seems the main reason for the increasing incidence of Diabetes. The impact of Diabetes Mellitus on health care organizations is very high. As an example, the Diabetes surveillance system of the U.S. National Centre for Chronic Diseases (http://www.cdc.gov) reports that the number of office visits to physicians increased of about 70% in 15 years from 1983 to 1996 (during this year the visits have been 63948 thousands). The costs for managing Diabetes is obviously very high, too. The European study CODE-2 has calculated that direct medical expenditures for more than 10 million european patients is more than 28 billion €, and that the largest cost category is hospitalisation. Moreover, the presence of Diabetes related complications highly increases the cost of patients' management [8,9,10].

The Diabetes Mellitus management plan is formulated as an individualized therapeutic alliance among the patient and the members of the health care team. The fundamental part of the care process is represented by the home care activities carried on by the patient. Home-care comprises the self-monitoring of blood glucose and the self-administration of drugs, such as insulin and/or oral hypoglycaemic agents. The data collected by patients and the overall status of the patient are monitored by health care providers through periodical control visits (every two to six months). Such visits may be carried on by GPs or specialists, in dependence on the severity of the disease. In addition to those *diabetological* visits, other visits and exams may be scheduled, such as retinal screening and EMG, as well as colloquia with dieticians and psychologists. Typically, several actors and organizations cooperate in the patient's care process.

A strong interest has been given to the definition of ICT-based systems devoted to the management of Diabetes Mellitus, mainly in the areas of Electronic patients' record, Decision support systems and telemedicine [5,11,12]. Our group has gained experience in the implementation of a multi-access system for patient's management which embeds telemedicine and EPR functionalities and guideline based patient handling. The current version of the system has been evaluated in a clinical study with very good results in terms of clinical outcomes and patients' acceptability [12]. In this paper we will describe an extension of such a system: the extension has been designed and implemented to cope with the inter-organizational communication needs which emerges taking into account all the aspects of diabetes management.

System architecture

In this paper we propose an infrastructure that enables inter- and intra-organizational communication through a Careflow Management System (CfMS) [6] that, on the basis of the available best practice medical knowledge, is able to coordinate the care providers activities. The final goal of this architecture is to provide Health Care Organizations (HCO) with technical solutions which should enable them to improve process efficiency, outcomes and quality of care. Such a technological infrastructure is the basis of a new system for managing both type 1 and type 2 Diabetic patient; however, its basic components are general for any intra- and inter-organizational communication needs in chronic patients care.

In the system architecture herein presented, the CfMS acts as a component of the Health Information System (HIS). A CfMS, according to the glossary defined by the Workflow Management Coalition (WfMC) [13], is a system that completely defines, creates and manages the execution of Careflows (Cfs) through the use of software, running under the control of one or more Cfs engines, which are able to interpret the care process definitions, interact with Cfs participants and, if required, invoke the use of IT tools and applications. A CfMS involves dedicated procedures through which administrative and supervisory tasks, such as documents sharing and information or assigning commitment for task execution, are passed from a participant to another according to a process definition. This consists of a network of activities and their relationships, criteria to indicate the start and termination of the process, and the information about the individual activities. Summarizing, a Cf process definition specifies which tasks need to be executed and in which order [6]. Cfs are *case-based*: a Cf instance is the process execution of a Cf for a particular patient. When a new instance of Cf takes place, the generic task will be defined as *work item* (a work item is a task executed for the care of an individual patient). Resources, either human or non-human, are requested to execute work items and the CfMS manages their allocation. They are grouped into classes. An activity is defined as a work item executed by a resource. The resources class referring to the capabilities of the HCO's members are called *organizational agents* and those referring to the structure of the HCO are called *organizational units*. Organizational agents are members of an organizational unit and may play one or more roles. So organizational agents execute activities within organizational units, use resources (material, biomedical instruments, system's services, etc.) and have a set of rules defining how to communicate with other agents in the organization. The use of a CfMS ensures an efficient and effective management of a care process within an organization.

The system described in this paper is able to manage a Cf both within a single organization and across organizations that are cooperating in the overall care delivery process. Figure 1 describes the general system architecture. Our goal is to set up a link between two or more organizational units belonging to one or more organizations. The Cf that defines the care process should be based on an international guideline defining which tasks should be executed for saving resources and achieving the best possible outcomes. A cross-organizational workflow has been designed and developed to manage the communication between agents, internal and external to the main organization responsible for the delivery of care. This system allows both the main organization to offer/use a large set of services, even provided by operational units belonging to other organizations, and the patients to be guided through different service points [14]. This could represent conceptually a serviceflow for chronic patient.

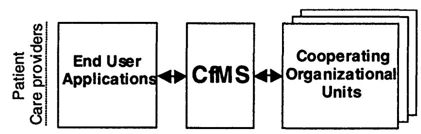

Figure 1 - The system architecture.

The coordination of a large number of people belonging to different organizational units, as suggested by Hans Weingand et al. [15], required mutual well defined agreements and commitments between the parties involved. They may be formally represented by "contracts". Contracts allow an organizational unit to use services offered by another unit that can be located either inside or outside the organization to which it belongs. Moreover, contracts explicitly represent the result of a negotiation process through which the two units agreed upon the service attributes. They may include commitment time, quality of service, time of delivery, shared terminology, privacy policy and other features. Contracts establish a tight link between organizational units without requiring mutual knowledge about reciprocal work processes.

Contracts should be described in an electronic form in order to be easily communicated and interpreted. EbXML [15] is a recently proposed XML-based standard to represent contract definition and specification.

The system we propose, thus, supports the connection among end-user applications (used by Cf participants), a Cf designed for a specific category of patients, and cooperating organizational units distributed on the territory. The CfMS represents the best practice knowledge suitable for the management of those patients, and optimises the use of end-user applications components, such as EPR management systems, and interaction between agents involved in the care process (e.g. patients, nurses, clinicians, etc.)

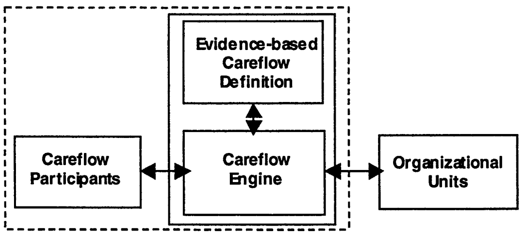

Figure 2 - The CfMS components.

The Cf engine interprets and controls the execution of the evidence-based careflow process and interacts both with the careflow participants and the organizational units, as described in Fig. 2. The CfMS allocates resources and manages the work items distribution, dealing with all the possible exceptions arising during the instance execution and generating worklists made available for care providers via the end-users application. This application contains forms for data entry, data retrieval and visualization. The communication with external agents (outside the organizational unit) is made through a cross-organizational units communication manager, which sorts out requests, based on contracts, to a specific organizational unit. Using contracts, as suggested before, the Cf doesn't know in which way the requests are worked out, but it is only interested in the results (for example, in our case, clinical reports, specialists advices, etc.). Such results are stored in the EPR and made available to the Cf participants through their end-user interfaces.

System implementation: managing Diabetes

As mentioned above, our work was aimed at integrating a multi-access system for Diabetes management into a cross-organizational CfMS. Such a system represents the end-user application of the architecture described above.

The Cf model of the Diabetes management process is described on the basis of a guideline developed by the American Diabetes Association (ADA) [16]. The model of the process has been formulated using ORACLE Workflow™ in accordance with the WfMC standards. Figure 3 shows the topmost view of the care process (left part) and a more detailed view of the *Management Plan sub-process* (right part within the dashed box).

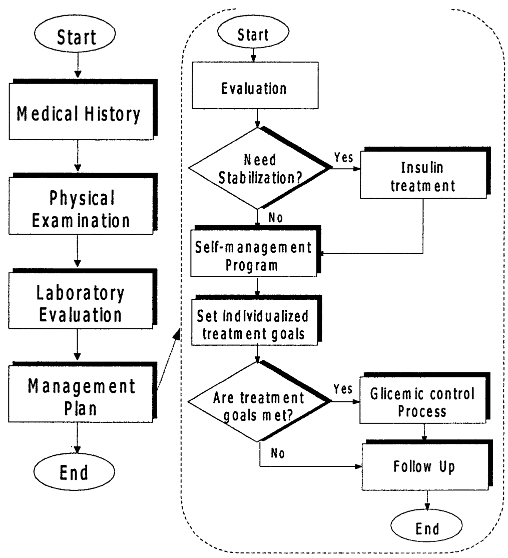

Figure 3 - The careflow model of the diabetes management process.

The care process starts with an initial evaluation of the patient's status, which consists of a comprehensive ***Medical History***, a detailed ***Physical Examination*** and a ***Laboratory Evaluation.*** This evaluation is useful for obtaining a complete patient's clinical status picture in order to detect possible diabetes complications and to classify the patient before the ***Management Plan*** begins.

As mentioned in the previous section, Diabetic patients should be managed by a physician-coordinated team, which includes Cf participants: physician, nurses, dietitians, pharmacists, and other health professionals with expertise in diabetes. Also the patient and his/her family need to be included among the Cf participants since they must have a central and active role (patient empowerment). In addition to the continuing care, preventive care and long-term screening are necessary for managing complications. The guideline suggests that examinations should be repeated annually, more frequently if there is a progressing complication. The complete annual screening should include lipid assessment, foot and eye examination, test for the presence of microalbuminuria, and any other tests the physician thinks could be necessary.

One of the most important aspects in managing diabetes care is to control the effects of the delivered therapy by monitoring individual patient blood glucose levels. The multi-access service developed by our group allows patients to send the blood glucose readings to the care centre using a smart modem, provides several tools for data summarization and analysis and supports the communication between patients and care providers through a dedicated messaging system. The care protocol requires that periodically patients send data to the clinical centre in order to allow care providers a continuous check of their metabolic control. Each Cf participant can access the monitoring data through different modalities. In particular, patients data are available for textual and graphical visualization, for simple reports generation and for performing different kind of statistical analysis. An important task performed by the Cf is the automatic evaluation of home monitoring data, as soon as they are sent to the diabetes management center, in order to detect potential critical situations that should be notified to the care providers or that could require further clinical investigations. This analysis calculates several descriptive statistics (i.e. arithmetic means, standard deviations and the highest and lowest values in a given period of time), performs data interpretation through the extraction of patterns of clinical importance and consistency checking. The goal of this kind of analyses is the evaluation of the discrepancies between what expected and what observed and, if necessary, of the circumstances which gave rise to the discrepancy. Such analysis allows health care providers to extract the evidence implicitly stored in the medical record and provides an effective support for the care-team.

If the Cf notices that the patient is not responding in the expected way to the therapy (e.g. hyperglycemias and hypoglycemias are too frequent) it generates a guideline-based suggestion to the physician about the need of a therapy modification. The therapy changes are then communicated by the CfMS to the patient through the dedicated messaging system. Figure 4 shows how the therapeutic scheme needs to be modified. It is communicated to the patient via the end-user application.

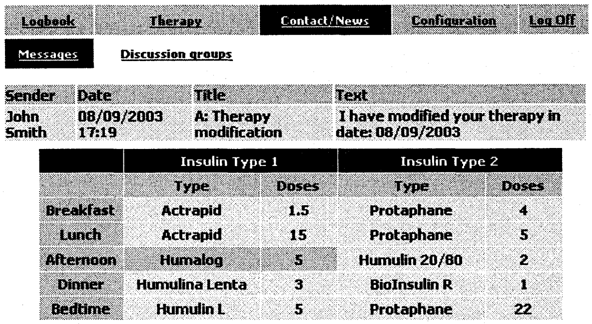

Figure 4 - An example of a therapy modification message sent to a patient. The interface shows the changed therapy doses with a different background color (in this example the afternoon Insulin Type 1 dose is changed by the physician).

Another important goal of the diabetic patients monitoring management is the prevention of long term complications.

In order to help physicians and patients in the management of the long term screening, the CfMS schedules periodic visits based on the patient's care process history. As described above, some clinical checks are periodic, so when the guideline prescribes a specific visit, the CfMS manages the request to the organizational unit providing that service. The communication between the CfMS and the external organisational units is carried out by an ICT tool purposely developed to manage the contract negotiation process.

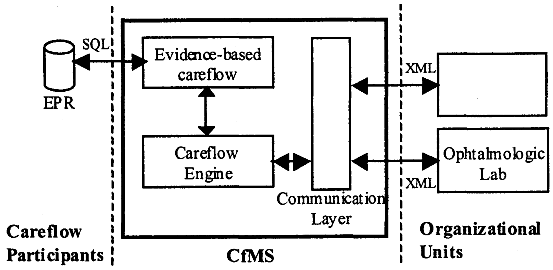

Figure 5 - The interaction among the main components of the system. The communication layer manages the XML documents exchanged with the organizational units. The EPR is the repository of the information used by the careflow participants and the CfMS for the care process management.

As an example let's consider all the steps of the retinopathy screening management. The first step consists in sending the request of a specialistic visit to the responsible organizational unit; in our example the communication tool, triggered by the CfMS, sends a message to the ophtalmologic laboratory. This request takes place sending an XML document defining the terms of contract: type of visit, patient data, urgency and the constraints on the execution and notification times.

The laboratory books the required visit for the patient and replies by sending an XML document to the communication tool containing time and scheduled visit date. The CfMS stores the data in the EPR and informs the patient and physician using the end-user applications: in particular an e-mail is sent to both the patient and the physician which is also available through a web and voice mail service. When the visit has been executed, the lab sends back an XML document with a clinical report of the visit results, as stated in the contract. The report is recorded in the database and notified with a message, by the CfMS, to both the caring physician and the patient, as shown in Fig. 6.

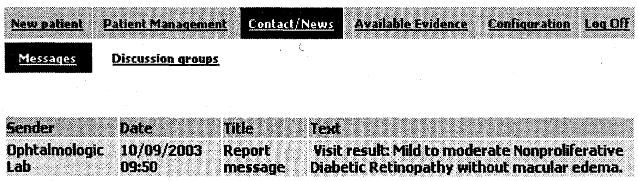

Figure 6 - An example of a visit report sent to the caring physician via e-mail.

Following these procedures all the data related to a specific patient and to the delivered care process are stored; at the same time the CfMS takes care of the overall process execution, of its adherence to the guideline and of the timely cooperation of each needed Cf participant. The architecture and functionalities herein presented are currently under evaluation and we foresee their clinical test in the near future.

Conclusions

The management of chronic disease is a complex task, which requires the interaction of a large number of actors. An innovative design of modular HIS is mandatory to manage such kind of complexity. A number of interesting criteria which helps the design of such systems can be derived from the guidelines proposed by the Institute of Medicine report on a "New Health System for the 21st century" [17]. In such a report it is stated that health care (and therefore its information systems) should be i) knowledge-based, ii) patient-centered, iii) systems minded. The full exploitation of a CfMS enables to reach all those three goals. CfMS are "by definition" knowledge-based, being based on explicit models of the process of care; the integration of CfMS, EPRs and telemedicine systems can be made effective through a patient-centric concept of health care; finally, the application of a CfMS able to interact with other organizations (and, if needed, with other CfMS) in complex working environments, explicitly takes into consideration the constraints provided by individual HIS. In this paper we have shown how a CfMS may be integrated with a multi-access system for diabetes management within a complex inter-organizational infrastructure. This system has been designed to better implement the multifaceted interventions which are needed to tackle with such an important and socially relevant disease [18]. Other relevant chronic disease, such as hypertension and peritoneal dialisys, will be considered in the near future to apply and test our proposed architecture.

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