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DIABCARD Core System - A Chip Card Medical Information System For Diabetes Care

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Abstract: A chip card based medical information system was developed as a good possibility to create a portable electronic patient record. The produced software module provides an on-line, portable diabetes medical record information system. In particular the patient data card makes the up-to-date patient's record available whenever needed. The developed Core System includes a patient record management system that has the ability to handle topics such as medical anamnesis, administrative, medical and physical examination data. Issues tackled were simplicity, data security and reporting. Customization and internationalization were also covered by presenting a novel approach using native initialization files. Proper care has been addressed during the development of the software modules for matters of security, data integrity and confidentiality.

1. Introduction

Effective patient treatment requires the healthcare personnel to know the patient's accurate and complete (as possible) medical history. Patients may be put at risk if additional treatment is unknown. The use of a smart card for storing part of the Computer-based Patient Record (CPR) renders this information available when and where it is needed. The long-term goal of the DIABCARD project is to improve the quality of care in chronic diseases by applying state-of-the-art technology for documentation and communication [1]. The DIABCARD installation is based on the improvement of inter-hospital communication, communication between diabetes centers and between diabetes centers and GPs. The architecture of the DIABCARD is flexible and adaptable to technological advance of the chip card [2]. The medical documentation of the Chip Card based Medical Information System (CCMIS) is based on a common set of terms and definitions compliant to the EU/G7 specification and DIABCARD Data Set. These definitions were also used in other projects such as EURODIABETA, DIABCARE, and DIABCARD and agreed upon by the medical partners of the DIABCARD-3 project [1,3,4]. The St. Vincent Declaration includes a commitment to improve the quality in diabetes care on a continuous basis [5]. Databases for diabetes management can be administered in two ways: (a) as a population register and (b) as a clinical management system. The first approach is designed for people living in a particular place and is mainly used for annual medical review, like the Dialog system [6]. The second one (clinical management system) is incorporated into the clinical process and the main target is the improved function of the administration of care.

The success of any database system for diabetes care is dependent upon several critical factors like the co-operation and continuing involvement of physicians, the

acceptance and use by them of a standard data set, user friendliness and the ability to modify the system [7]. These factors can be accomplished by object-oriented approach, which has received increased attention recently especially in medical computer environments [8,9]. One reason, is that it seeks to mimic the way that models of the real world (entities) are formed, constrains are put on them and relationships among objects are defined [10]. In contrast to the procedural way of thinking, it de-emphasises the underlying computer representation by handling *objects*, which are used to symbolise real-world entities and their interaction [11, 12]. Every object can encapsulate a state (attribute) and a behaviour (method) and allow only a pre-specified set of operations to act upon itself.

2. Methods

A CCMIS was used as a good possibility to replace paper records. The Patient Data Card (PDC) makes the up-to-date patient's record available whenever it is needed. The analysis stage was centralized in the development of a patient record management system that can handle topics such as administrative, medical anamnesis and physical examination data. Proper care has been paid during the development of the software modules for the following matters: **(a) Simplicity:** The system has to deal with a large amount of data fields of various types and also it was a prerequisite that the program should be user friendly. So the MS-Windows'95 environment was chosen for the development of user friendly forms and functions that the software had to cover. **(b) Customization and Internationalization:** These are two other issues that are handled by the program through the use of external "table set-up files" (TBL files) which contain data field descriptions and form properties. During the form creation stage of the software, the above files are used to dynamically produce the final output of the form on the screen. The customization of the TBL files allows the system to have a multilingual dimension and offers the ability for each site to setup the system environment parameters according to local terms that are used in routine procedures. **(c) Data security:** In order to achieve data security, a user management system was developed to prevent unauthorized persons from accessing the patients' data. **(d) Reporting:** A flexible reporting system was developed giving the end-users the ability to create and customize their own reports according to their needs using Structured Data Entry (SDE).

The CPR handles the following functionalities: administrative, patient record administration, document administration, data import/export, CPR dynamic browsing, user defined reporting, Chip card input/output and user management.

2.1. Analysis and Design

The medical record of the DIABCARD Core System is *Document Oriented.* Every record of medical data items is linked to a record in a document table, the document is linked to a table of patient visits and every visit is linked to a patient. This means that for every patient's visit the user has to fill out documents as in every routine of a paper based medical record system. Each document can have one of the following states: "created", "in-work", "signed" or "rejected". Once a document is "created" it can be edited ("in-work") until it is "signed". Signed documents can only be "rejected" and they can not be deleted from the medical record.

The data structure of the DIABCARD Core System was based on the DIABCARD Data Set version 2.2. To enforce interoperability the Data Set took into account the data and existing data sets from other projects related to the DIABCARD, like CHIC for the socio-demographic data [13], the EUROCARDS Working Group 3 for administrative data [14],

the approved EURODIABETA Diabetes Data Set [4] and the DiabCare Basic Information Sheet (i.e. the implementation of the St Vincent Declaration) for medical data [15].

The database system manages data tables of patient data, patient visits, documents and lookup tables. The field names for the EU/G7 data (administrative and emergency data) and the Medical data match the ID of the corresponding item in the data set so that they can be easily accessed in the future from other applications. Every type of document has a corresponding TBL control file that defines which items will be included in the document. These TBL files can be altered through an included tool that guides the administrator through user-friendly dialogs and multi-choice selections. So each site can customize the program according to language and local terms that are used in routine procedures.

2.2. Chip Card Access

The file structuring on the DIABCARD chip card implements an ISO-7816 file system. EU/G7 interoperable data, ensuring interoperability with other similar projects, are stored in three distinct Elementary Files (EF): (a) EU/G7 card data, (b) EU/G7 administrative data, (c) EU/G7 medical emergency data. The contents of these data sets are defined within the DIABCARD DataSet. While the DIABCARD Data Interface provides access to the contents of these files via predefined tags. DIABCARD medical data, not contained within the three interoperability data sets, are stored in one single EF.

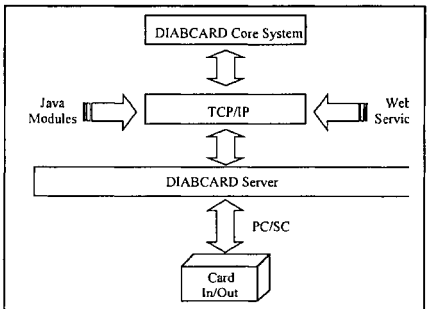

Figure 1: The DIABCARD Core System/DIABCARD Server interface

The DIABCARD Core System is using the DIABCARD Server developed by ACG SmartGate for accessing the chip card through a TCP/IP Interface (figure 1). This Interface can be integrated into existing medical information systems, allowing access to the chip card data through PC/SC interface. Also, the DIABCARD Server (not described in this paper) ensures that application programs are independent of the used chip card reader, chip card operating system, security algorithms and of details concerning data location and file structure on the card.

The data structures for the communication with the DIABCARD Server are coded in the form Tag-Length-Value (TLV). The tag contains of 1-4 bytes and is the indication of the data object. The length indicates the length of the bytes and of the value field and contains of 1-4 bytes. The value field contains the necessary data in byte coding or in TLV coding, when the data objects are put together. The field length determines the size of the necessary data.

3. Results

The system is currently being tested by clinicians in Greece, Spain, Italy, Germany and Austria. The environment is proven to be user friendly and was initially accepted by the clinicians. Complexity of the DIABCARD data set seems difficult to be handled by the users that prefer to deal with smaller amounts of data. Thus two general documents, the B.I.S. (Basic Information Sheet) and D.P. (Diabetes Passport), that can be filled in or created automatically from the common data of other documents, are the only data subsets that are for the moment agreed to be stored on the chip card.

Also the Custom Document Creation Wizard tool and the Document Customization tool that give the end-users the ability to create custom documents in their own language was another advantage that proved to be very important for the system users. Moreover, the reporting functionality was well accepted by the physicians, because it follows a well organised structured data entry through a field tree of possible user choices with the combination of free text input.

4. Discussion

In conclusion, the produced system can provide an on-line, secure and portable diabetes medical record that uses the advanced technology of chip cards. It offers extensive management of large amount of data fields in a user friendly multilingual man machine interface, user manageable reporting system with the ability to dynamically expand the internal data structure and functionalities. Because of the object-oriented design of the Core System the application can be easily upgraded and extended taking advantage of the work that has already been done. New Document objects can be derived from existing ones to satisfy special needs that may come up in the future.

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