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A Scheme for Assuring Lifelong Readability in Computer Based Medical Records

Yasushi Matsumura[a], Noriyuki Kurabayashi[b], Tetsuya Iwasaki[b], Shuichi Sugaya[b], Kanayo Ueda[a], Takahiro Mineno[a], Hiroshi Takeda[a]

[a] *Department of Medical Informatics, Osaka University Hospital, Osaka, Japan*
[b] *Medical Information System Business Development Office, Solutions Group, Fuji Xerox Co., Ltd., Tokyo, Japan*

Abstract

Medical records must be kept over an extended period of time, meanwhile computer based medical records are renewed every 5 -6 years. Readability of medical records must be assured even though the systems are renewed by different vendors. To achieve this, we proposed a method called DACS, in which a medical record is considered as an aggregation of documents. A Document generated by a system is transformed to a format read by free software such as PDF, which is transferred with the document meta-information and important data written on the XML to the Document Deliverer. It stores these data into the Document Archiver, the Document Sharing Server and the Data Warehouse (DWH). We developed the Matrix View which shows documents in chronological order, and the Tree View showing documents in class tree structure. By this method all the documents can be integrated and be viewed by a single viewer. This helps users figure out patient history and find a document being sought. In addition, documents' data can be shared among systems and analyzed by DWH. Most importantly DACS can assure the lifelong readability of medical records.

Keywords:

Medical record system, Hospital information system, Information storage and retrieval

Introduction

Electronic medical record systems (EMR) have come into practical use. EMR is more convenient than paper based medical records because the carrying of paper files of medical records becomes unnecessary, and accessibility to medical records is greatly improved. A medical record is a record of observations and process of treatments of a patient. In Japan, there is a legal obligation to keep medical records for at least 5 years after the patients' treatment has ended. Some patients have been treated in a hospital for more than 20 years. Thus their medical records must be kept for an extended period of time. On the other hand, EMR has to be renewed every 5 to 6 years. On system renewal, not only hardware but also OS and application software are renewed. An EMR is composed of several systems provided by different vendors, especially in a large hospital. These systems may have to be renewed by different vendors due to changing needs of hospital staffs. In this circumstance, in order that the data stored into the system can be viewed persistently, it must be stored by a consistent well-considered method. Otherwise, when the application software is renewed, the data stored in the old system cannot be viewed. EMR already started without much consideration for the long-term readability of medical records.

To solve this problem, we propose a document based electronic medical record, considering a medical record as an aggregation of documents. A document's information consists of the document body and its meta-information. The data form of the document body is transformed into PDF, JPEG, TIFF or DocuWorks, etc. which can be read by free software universally available. Documents' meta-information is collected in a unified format. In the field of medical imaging, the concept of PACS (Picture Archiving and Communication System) is well-known and widely used. In PACS, image data composed of image body data and its meta-information is managed uniformly, so any images can be viewed by a single viewer. Our proposed system is similar to PACS where documents are substituted for images. Thus we name this system DACS (Document Archiving and Communication System).

By collecting all the documents of a patient, it is possible to view them by a single viewer. In the existing EMR, patients' clinical data are stored in different systems. Each system sets up a web system to let users view it from the patient's clinical record view window. By this method it is possible to access a requested document. However, it is difficult to comprehend a patient's entire clinical history, because different kinds of needed documents can be accessed only from their own window. Hospital staff needs to comprehend a patient's problems and requirements in a short period of time when they participate in the patient's medical care. In this case, they need to know what kind of documents exists for the patient. In addition, they have to view related documents with the one

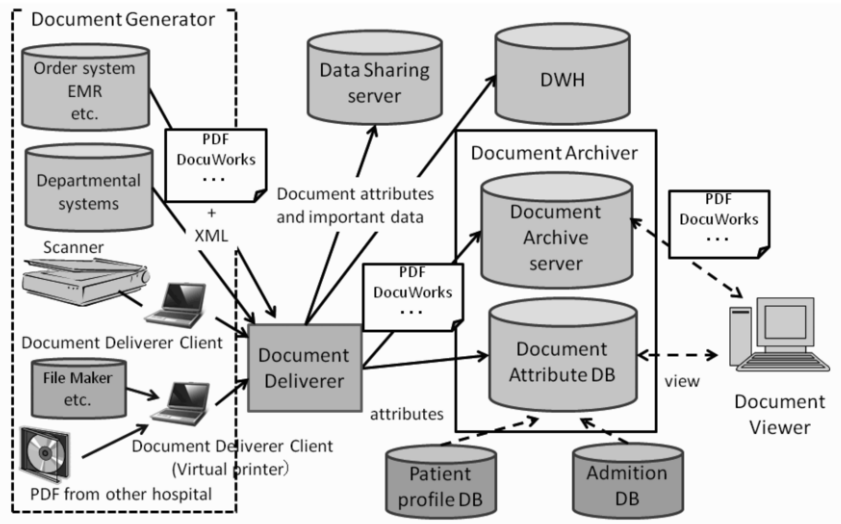

Figure 1- Basic configuration of DACS

currently being viewed, even though they are generated by different systems.

If medical record data is handled by documents, a worry arises that the data in the documents might be difficult to process. This data is sometimes required to be shared among different systems. There is also a request that the data in the documents be used for analysis. To fulfill these requirements, we proposed a method for collecting important data in a document with document's meta-information.

Methods

Fundamental Concept of DACS

In DACS, medical records are handled as an aggregation of documents instead of data. Typical document types are examination reports, operation records and discharge summaries which are created for respective events. In addition, chronologically continuous data is converted into a series of documents by setting an intersection. For example, a progress note that is written continuously for an inpatient is divided by day and by the department of the creator into a series of documents.

The basic configuration of DACS is shown in Fig.1. Systems that generate documents are called Document Generators. All the generated documents are transferred to a Document Deliverer. Next, the Document Deliverer transfers them to the Document Archiver, the Data Sharing Server, and the Data Warehouse (DWH). The Document Viewer, which runs on each EMR terminal, accesses Document Archiver to display documents.

Document Body and its Attributes

A Document generated by a system is transformed to a standard format read by free software. In our DACS implementation, PDF, JPEG, TIFF or DocuWorks are used for said format. Document information is separated into a document body for readability and its meta-information.

Document meta-information consists of document attributes. The mandatory attributes are patient ID, document class code, event date, and department code. Document class code is unique to each document class in a hospital. The document class is defined by the smallest granularity. They are grouped into super-classes by the external table file, because a classification scheme varies according to the requirements of the subsystems.

Event date is the date most appropriate for the document. For example, the event date of an examination report is the date on which the examination took place rather than the date on which it was created. Documents such as discharge summaries and flow-sheets are records of a certain period of time. For these documents, attributes for the start date and end date are provided. In case two or more documents of the same class were created for the same patient on the same date, the documents need to be identified by time. So time attribute is also provided.

A document sometimes has several departments as an attribute, such as the department that placed the order, that created the document, or where the patient was hospitalized. A suitable one is selected for each document class.

In addition to the aforesaid mandatory attributes, a numbers of optional attributes are defined. The patient profile information, such as patients' names, can be retrieved from the system through patient ID. Although there is important information

such as class of inpatient/outpatient or document's author information, some of the latter are practically unavailable due to documents' origin. So we did not make them mandatory. We limited the mandatory attributes to those required for the Document Viewer to be described shortly.

In order to share with other systems important data included in a document, and use it for data analysis, such data is extracted from a document. The data is presented by item code, item name, value name and value code if it exists. The item code must be assigned uniquely in a document class. Thus uniqueness of an item can be ascertained by the item code along with the document class code.

These documents' attributes and important data in the documents are conveyed by the XML format.

Transferring Documents from Document Generators

There are 4 types of Document Generators. 1) Physician order entry system, EMR, etc. 2) departmental system 3) document scanners 4) virtual printers.

Types-1 and 2 are intersystem connection type and are essentially the same. In most settings, printed output image is available, so the image is converted into PDF format and the document's meta-information is embedded in the prescribed XML format when it is sent to the Document Deliverer.

Intersystem connection in Type-2 is typically a transmission of a report. An originating system generates a PDF file from a print output image, and an XML file including the document's meta-information. Then it transmits them to the Document Deliverer when the report is approved.

In Type-3, a scanned image is transformed to DocuWorks format. Because QR code is printed on sheets, the document's meta-information can be recognized by reading it. This DocuWorks file and the XML file including the document's meta-information are transmitted to the Document Deliverer. We call this module a Document Deliverer Client. Documents are then transmitted to the Document Archiver and digitally signed and time-stamped using XAdES [1].

The virtual printing system of Type-4 is similar to Type-3. When the virtual printer outputs a print image using its driver, a DocuWorks file is transferred to the Document Deliverer Client. In case patient ID, event date, and document class ID are set at predefined positions in header and footer of an output document, they can be read automatically. In case these data are not set, they are input manually. In Types-3 and 4, a DocuWorks file together with a prescribed XML file is transmitted to the Document Deliverer from the Document Deliverer Client.

Delivering Documents

The Document Deliverer performs the task of delivering documents received from Document Generators. The Document Deliverer lightens the load of Document Generators for document archiving. FTP, CIFS and SOAP are available protocols for transferring document information from Document Generators to the Document Deliverer. Although bidirectional communication over SOAP is reliable, most developers prefer FTP because it is easy to implement. The Document Deliverer receives a document body file and its meta-information in the XML. It registers the document body and its meta-information to the Document Archiver. The Document Deliverer also delivers the data received to the Data Sharing Server and to the DWH. Compared to the method in which each Document Generator directly sends document information to the Document Archiver, the Data Sharing Server and the DWH, data transmission via Document Deliverer greatly reduces the load of Document Generators.

Preserving Documents

Document body and document attributes are stored into the different databases in the Document Archiver. No medical specialization is needed for the server in charge of the document body. Here we employed a Document Management System (DMS) product from Fuji Xerox. On the other hand, for the database for document attributes medical specializations are necessary. This database is needed for the Document Viewer. Besides information received from the Document Deliverer, patient profile information and admission history are also necessary. These are obtained from the hospital information system.

Viewing Documents

There are two ways for viewing documents. One is focusing on a patient to view various documents of that patient, and the other is focusing on a document type to view the documents of patients. The former is the prerequisite for EMR, while the latter is a function required for department operation. We call these viewers Medical Record Viewer and Register Viewer, respectively.

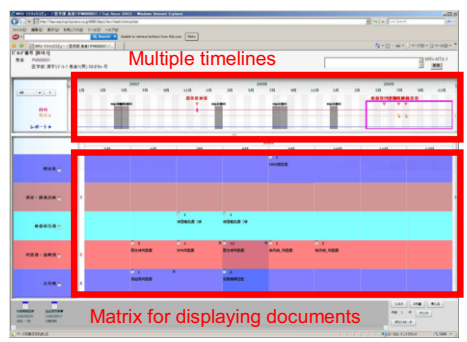

Figure 2- Matrix View

A Medical Record Viewer has two types of viewers: Matrix View which shows documents in chronological structure, and Tree View showing documents in class tree structure. The Matrix View (Fig.2) is designed to overview the patient's medical history with information over half a decade shown on one screen. Multiple timelines are displayed in the upper pane. Patient encounters (creation of progress notes) in each department and examinations carried out for the patient (submission of examination reports) are marked on timelines. Hospital admissions and important event such as operations are also dis-

played. Documents in the area specified by a thick frame on the timeline pane are browsed at the lower pane. The lower pane displays the documents in matrix form. Rows correspond to document classes and columns indicate periods. Because many document classes exist even in one patient, all the items presented in rows cannot be seen without scrolling. So we design a method to accomplish this. In this method, the thickness of the layer changes flexibly according to presence of documents. Because many documents are rarely generated on a same day, most of them can be viewed without scrolling.

When a document is designated in this pane, a browsing window called Focus View (Figure 3) is opened to display the content. The Focus View is set double-screen as default.

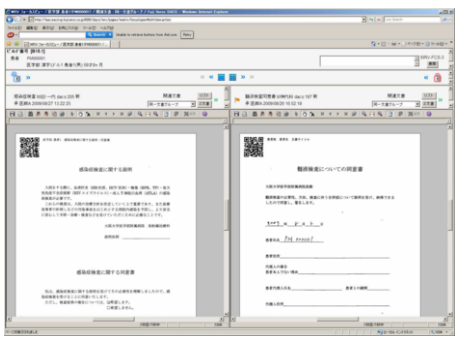

Figure 3- Focus View

Tree View is designed for searching a document. The document to be searched can be accessed according to date, document class, inpatient or outpatient by tracing classification folders.

Register Viewer is a viewer meant to read through documents in a specified class. It needs access control. For example, doctors in charge can access all the documents generated by their department. On the other hand, they cannot see the documents generated by other departments as a whole. Additionally, the hospital staff who engage in a special work for patients should be permitted to access the documents created by the staff. For example, the technician in charge of echocardiography should be able to view all the echocardiography reports. However, other hospital staff should not be permitted to access this view.

Printing Documents

Fuji Xerox's DMS has the function of outputting all the files of a patient for a designated period to a predefined directory. Numbers representing orders for print are set in the filename of the output files so that the print module can print them in a predetermined order.

Shared Database and DWH

By storing data in the Data Sharing Server, the data can be shared among different systems. In spite of the variety of data types, all the data can be stored in the scheme of item code, item name, value name and value code with the originated document's attributes such as patient ID, document class code, and event date. In this data scheme, one value is saved in one record. The primary key of the database file is a composition of the document class code and the item code. By linking with the table where the primary key corresponds to a concept code, items originated from different documents with the same concept code can be recognized as the same item. When no data in a document are set in the XML format, a fixed data is stored in the item code field in order to store the document's attributes.

The data scheme of DWH is the same as that of the Data Sharing Sever. Because not all of the important data is shared among systems, The Data Sharing Server keeps the limited items for few months in order to keep good response time. DWH, on the other hand, keeps all the important data and document's attributes sent from every Generator.

Results

We are now preparing for the renewal of the hospital information system of Osaka University Hospital which is going to start in January, 2010. It includes various types of physician order entry systems, medical record entries such as initial visit reports, progress notes, discharge summaries, etc. which are produced by NEC. In addition, there are many special departmental systems which are produced by different vendors. DACS is implemented in this new system. Most of the system is already in place. All of the clinical documents generated by various types of systems except for laboratory test results can be collected in the Document Archiver. For each Document Generator, to send documents by the proposed method, a program module for it had to be made. This method was so simple that all the systems in our hospital could make it. There were some systems that could not be customized. For these systems, the method of virtual printer was effective.

There are some paper based documents which originally cannot be digitalized. These documents also have to be collected for management by paperless computer based medical record. For these documents, scanning is practical and effective [2]. After scanning the document data are handled in the same manner.

Because all the documents are collected into the Document Archiver, they can be viewed by a single viewer. The Matrix View that we developed in this project is distinctive. The timelines of the Matrix View on which a constellation of clinical events marked will help users comprehend the trend of the patient's history by pattern recognition. The Focus View which is for seeing a document's contents has two screens. Thus the present one can be compared with the past one in the same document class. It can also view a discharge summary concurrently with examination reports during the same hospital admission.

Medical records are sometimes demanded for disclosure. In case of a lawsuit, all the medical records must be printed out for preservation of evidence. If some of them are missing, it may be regarded as concealing evidence. It is impossible for the EMR that integrates documents by web systems to print them out in readable order. Furthermore users can easily neglect to print out some part of the record. Because DACS ag-

lect to print out some part of the record. Because DACS aggregates all the documents, it is easy to print out all the records in a designated order without omitting anything.

Even though DACS is document based, important data in documents can be shared among different systems and be analyzed by DWH. We selected the data which may be used by other systems or be analyzed for clinical research in each document class. The requirement of our method is only to assure uniqueness of item code in each document. The vendors which develop the systems (Document Generators) can easily comply with this requirement and embedded them in the XML format.

The most essential point of DACS is to assure lifelong readability of medical record. Because the documents' bodies are viewable by free software, it will be read over a long period of time. Furthermore the structure of the document's meta-information is so simple that conversion of the data stored in a DACS to another new system is not difficult. Thus documents stored in a DACS will able to be viewed continuously.

Discussion

The scheme for securing lifelong readability of medical records is fundamental for management by paperless computer based medical records [3]. A medical record can be considered as an aggregation of documents. The essence of our method is that the document's body data is transformed into data forms which can be read by free software universally available and is collected with the document's meta-information.

For exchange of documents between systems, CDA (Clinical Document Architecture) is often used [4]. CDA is expected to be foundational for the realization of semantic interoperability for clinical statement. Our proposed method also uses XML as a conveyer of documents' meta-information, which corresponds to CDA header. Thus our method corresponds to a use case of CDA level-1 using external files. In order to share and analyze data, important data is also conveyed by the XML format. In CDA, data about patient is written in entry element in the part of the document body where code should be assigned as OID. In our method, the item code is simply required to be unique in a hospital. The concept code is assigned when the XML format is received by the Data Sharing Server or the DWH. That is because CDA aims at data exchange between facilities, code system used in CDA should be clearly demonstrated in the document. On the other hand, our method aims data exchange within a single facility. Thus it is easier to assign codes systematically after receiving a document. If the method for sending a document is complicated, it is difficult to collect all the clinical documents in a hospital. The XML format of our method is so simple that any system can easily generate it. It is speculated that it will take time for CDA to become widespread. Before that, our method is a practical solution.

Because DACS aggregates all the clinical documents, it enables users to view them concurrently even though the documents are generated by different systems. In paper based medical records, files for patients are separated according to inpatient or outpatient status. In computer based medical records, all the records for a patient can be viewed without decoupling. However, sometimes there is a lot of information even on one patient. We developed a document viewer system which automatically arranges clinical documents to help users figure out a patient's history and find a needed document.

The hospital information system of Osaka University Hospital consists of several server computers and more than 2000 PCs, which are connected by 1 Gbps network. On this hardware, physician order entry systems, document creating systems, a reservation system, PACS, various types of departmental systems, an accounting system, a physical distribution system, etc. are running. DACS is one of these applications. A hospital information system in a large hospital usually consists of many systems produced by different vendors. A hospital information system can be operated as EMR without DACS by showing clinical information by using web system. However, in order to integrate various types of systems that generate clinical documents, DACS is desirable. Furthermore, to secure medical record readability over an extended period of time, we had found our DACS method to be most practical.

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Address for correspondence

Yasushi Matsumura MD, PhD
2-15, Yamada-Oka, Suita, Osaka 565-0871, JAPAN
Phone: +81-6-6879-5900, Fax: +81-6-6879-5903
e-mail: matumura@hp-info.med.osaka-u.ac.jp