# An HL7 Version 3 Based Regional Diabetes Patient Record Project Developed in Japan

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## Abstract

*This paper describes a regional diabetes patient record project developed in Fukuoka, Japan. The project started in 2001. The outstanding features of the patient record system are as follows. First, we employed HL7 (Health Level Seven) Version 3 as a clinical information exchange protocol for standardization. Any communications among systems are implemented as HL7 Version 3 messages. This implementation of HL7 Version3 is regarded as the earliest practical use of it. For the implementation, we used 35 HL7 Version 3 message types, 7 of which are provided by HL7 while the rests are originally defined by the project. Second, we achieve the high level security based on PKI (Public Key Infrastructure). Every user, which is a healthcare provider or a patient, is issued an IC card storing his/her public key certificate and the corresponding private key. He/she uses it when logging on the system and signing patient records. We are now extending the patient record system in order that it can deal with genome information.*

***Keywords:***

*Electronic patient record, Diabetes mellitus, HL7 Version3, Public Key Infrastructure*

## Introduction

Diabetes Mellitus is now a social problem in Japan. The Japanese Ministry of Health, Welfare and Labor estimated the number of Japanese people that are diagnosed or suspected as more than 15 million, which is about one-sixth of the Japanese population. In such a social circumstances, we expect an EPR (Electronic Patient Record) network as one of the effective device to control diabetes.

This paper describes a regional diabetes patient record project developed in Fukuoka, Japan. The project started in 2001 that was the first year of practical EPR era in Japan. The Japanese Ministry of Economy and Industry made an annual budge of about 55 million dollars for development of regional EPRs in 2001. Twenty-six projects of regional EPR projects were funded by them. Our project is one of these project and about 1.8 million dollars were assigned for this project.

This project was organized by Fukuoka City Medical Association and Kyushu University Hospital. Figure 1 illustrates the concept of the project. The project aims at the management of total healthcare of patients with diabetes mellitus.

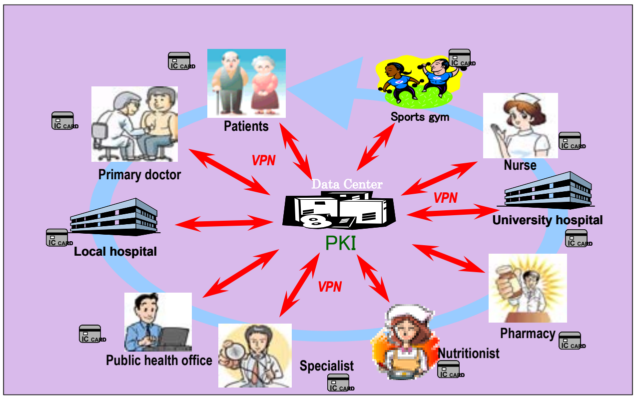


*Figure 1-Concept of our project*

## Materials and Methods

### Standardization with HL7

***HL7 Version 3***

One of the outstanding features of this project is conformance to HL7 (Health Level Seven). HL7 is a standard protocol for exchanging messages among information systems in healthcare domain. The system employs HL7 Version 3 as a clinical information exchange protocol for standardization[1].

HL7 Version 3 is its latest version. It is based on a consistent message development methodology and a shared information model (e.g. RIM; Reference Information Model) that is the source for the data content of all HL7 Version 3 messages. Because development of HL7 Version3 standard is now in progress, we conform to HL7 Version 3 ballot 1.

***RIM Database***

HL7 RIM is the source for the data content in every Version3 messages. In order to store any information on the Version3 messages effectively, we design and implement a generic HL7 RIM database. Any information represented by RIM is stored into the database and restored from it. It means that the database is not specialized for this project.

The version of RIM is 1.10[4]. We use PostgreSQL, which is one of the major open sourced database management systems.

To make the database generic, each RIM class is mapped to a relational table one-to-one. Every table has a primary key. An association between classes is implemented by using the primary key. An inheritance of RIM class is implemented by using schema inheritance function provided by postgreSQL. Each RIM data type except for abstracts data types such as **ANY** (Data Value) and **QTY** (Quantity) is also mapped to a relational table one to one. However, some atomic data types such as **BL** (Boolean) and **INT** (Integer) are implemented as native data types provided by PostgreSQL.

In order to process large number of tables effectively, data types are denormalized into RIM class tables as much as possible. For instance, data type of attribute **class_cd** of class **Role** is **CS** (Coded Simple Value). In this case, "**cs**" table corresponding to datatype **CS** are denormalized into the "**role**" table corresponding to class **Role** as shown in Figure 2. However, there are some exceptions. Collection data types such as **SET<II>** (SET of Instance Identifier) for attribute **id** of class **Role**, and data types that contain any

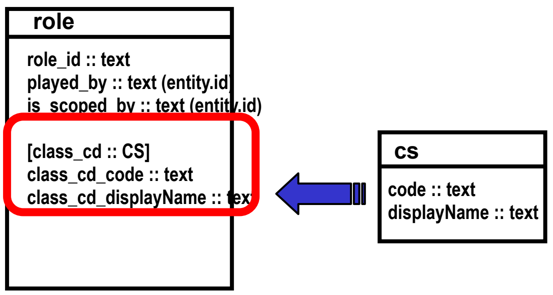


*Figure 2- Data type denormalization*

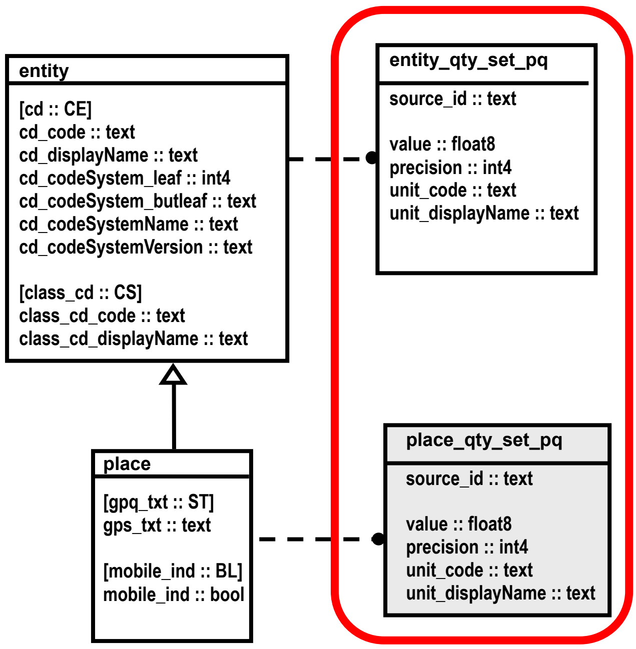


*Figure 3- Inheritance of a relation*

recursive reference such as **ED** (Encapsulated Data) are defined as a separate table from the class table.

When a class is inherited from a supper class and the supper class has an association to another class (e.g. a relation between tables), the subclass inherits the relation in the super classes. For example, "**entity**" table has a relation to "**entity_qty_set_pq**" table that corresponds to the attribute **qty** of class **Entity**. In this case, "**place**" table which corresponds to class **Place** (a subclass of class **Entity**) has a relation to "**place_qty_set_pq**" table that has same schema as the "**entity_qty_set_pq**" table as shown in Figure 3.

***Message Design***

In our project, we use 35 message types. They are categorized in the 8 domains shown in Table 1. Domains "Diet", "Physiotherapy", and "Patient Referral" are newly defined in our project. We use 7 message types defined in the HL7 Version3 ballot 1 for domains "Control", "Pharmacy", and "Laboratory". The rest of 28 messages denoted with boldface in Table 1 are newly developed based on the existing messages in the ballot.

*Table 1 – Summary of messages*

| Domain | Number of messages |
|---|---|
| Control | 2 |
| Query | **18** |
| Laboratory | 1 |
| Pharmacy | 4 |
| ***Diet*** | **4** |
| ***Physiotherapy*** | **4** |
| Medical Records | **1** |
| ***Patient Referral*** | **1** |

We show a design of diet messages as an example. Figure 4 shows a series of interaction of a diet order. A patient visits a healthcare institution and takes medical examination from a practitioner. The practitioner sends a diet prescription order to diet system, and a medical record is sent to the EPR database with the prescription order. When the patient visits a diet consulting office, a nutritionist obtains a prescription order for the patient, then, performs diet administration. Then, the nutritionist sends a result of administration as a diet event to the EPR client. When the patient re-visits the healthcare institution, the practitioner confirms the result and stores the medical record with the result. We designed 28 message information models (R-MIM; Refined Message Information Model) that express the information content for a message. Figure 5 shows the R-MIM for "Diet Order" message.

**Security based on X.509 PKI**

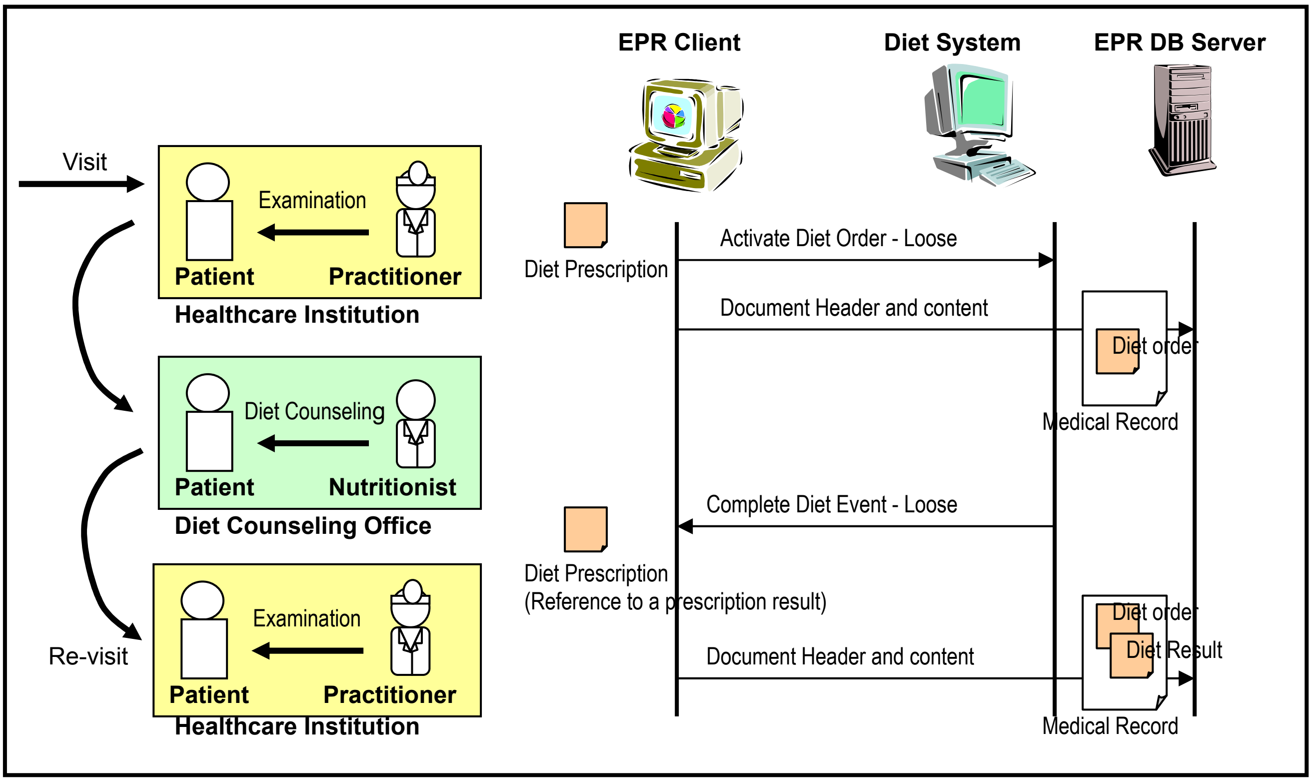


*Figure 4-A series of interactions of a diet order*

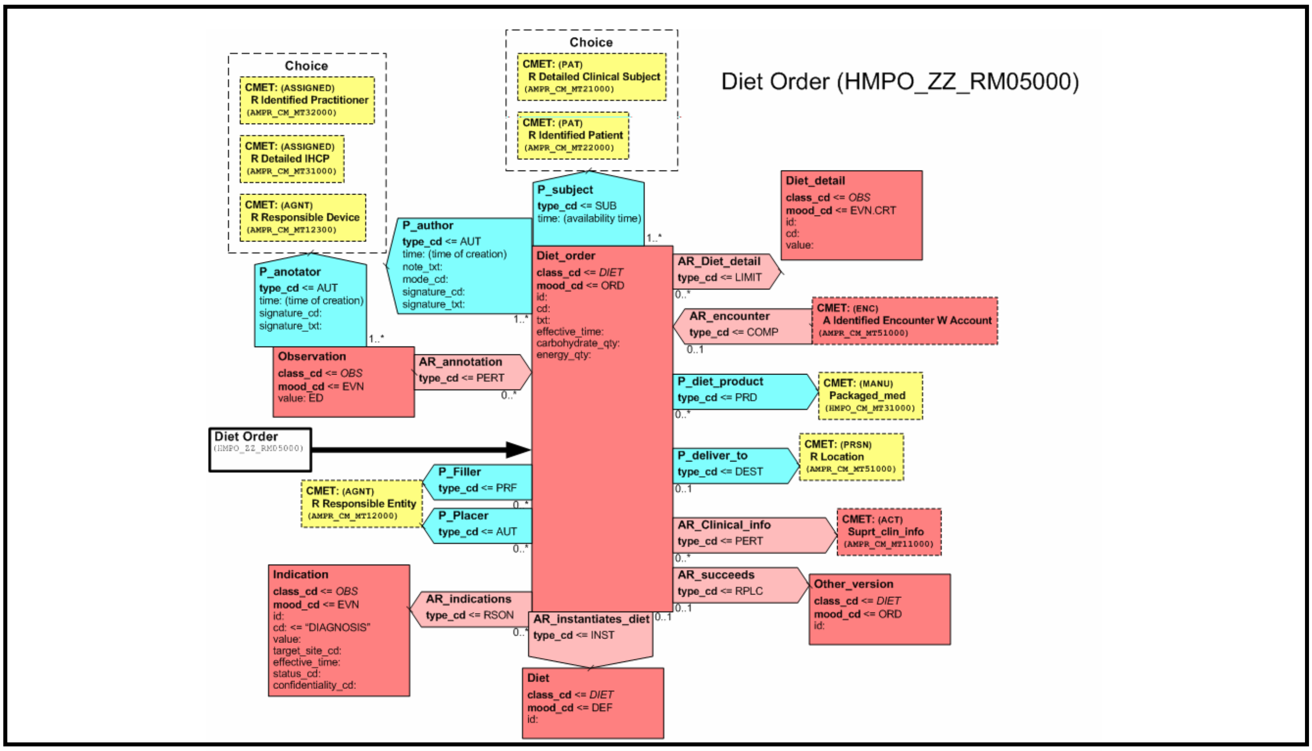


*Figure 5-Diet Order R-MIM*

The achievement of the high level security based on X.509 PKI (Public Key Infrastructure)[2] is another outstanding characteristics of the system.

For making use of clinical information across the healthcare institutes, standardization of data formats and vocabularies of representing clinical information such as HL7 are essential. In addition to them, digital signature is a critical key technology for making the clinical information to be exchanged secure and trustworthy. Efficient exchanges of authorized information with a digital signature in healthcare information networks require a construction of a PKI.

We set up single CA (Certification Authority) and issued public key certificates to every end user. The profiles of the public key certificates we used are illustrated in Table 2. Every user, that is, every healthcare provider and patient has his/her own IC card. The public key certificate and its corresponding private key are stored onto the IC card. User authentication and authorization are performed using two-pieces of IC cards, one of which is a healthcare provider's card and the other of which is a patient's card. In the system, a healthcare provider is not permitted to access a patient's healthcare records without the patient's IC card.

The IC card is used when a healthcare provider sign clinical document. In the system, every HL7 message is digital signed by using XML Signature technology[3].

*Table 2 – Profiles of the X.509 certificates*

| Properties | CA Certificate | End entity Certificate |
|---|---|---|
| 1. version | v3 | v3 |
| 2. serialNumber | Numbered by CA | Numbered by C A |
| 3. signature | sha-1WithRSA Encryption (1.2.840.11354 9.1.1.5) | sha-1WithRSAE ncryption (1.2.840.113549. 1.1.5) |
| 4. issuer | C=JP, O=Fukuoka, CN=DM EPR Project | DN of the CA |
| 5. validity | notBefore=x; notAfter=x+8 years | notBefore=x; notAfter=x+y years, y<=4 |
| 6. subject | C=JP, O=Fukuoka, CN=DM EPR Project | DN of the end entity |
| 7. subjectPublicKeyInfo | rsaEncryption | rsaEncryption |
| 8. basicContraints | CA=T; pathLenConstr aint is not specified | |
| 9. keyUsage | keyCertSign \| cRLSign | digitalSignature \| nonRepudiation |

**System Architecture**

Figure 6 shows the system architecture. The following steps describe how sender's clinical information is sent to a receiving system and stored into databases. First, an authenticated user enters clinical information in an EPR client. A "Version 3 Message Constructor" represents the clinical information as a XML Version 3 messages. A "Version 3 Message Signer" digests and signs the XML message. The signed message are then serialized and transmitted to the receiver. A "Signature Validator" validates the digital signature of the received message and decides whether the message can be accepted. Then, a "Version 3 Message Parser" parses and interprets the accepted XML Version 3 message and stores it into a RIM Database by decomposing the message into RIM objects. The message is also stored into a Message Tracker as a XML document for further references.

## Results

The system development and experimental evaluation had completed by February 2002. Forty-seven healthcare institutes in Fukuoka city cooperated in this project, including Kyushu University Hospital that is the largest national university hospital in Japan and Adult Disease Center of Fukuoka City Medical Association. Among them, 13 institutes are connected by ISDN telephone circuits while 33 institutes use PHS telephone circuits. These 47 medical institutes such as university hospitals, laboratory centers, pharmacies, and sports gyms share the clinical information on a patient thorough the electronic patient record network. This enables us to tie-up the clinical practice among the medical institutes.

Any communications among EPR systems of the project are implemented as HL7 Version 3 messages. In the HL7 Working Group Meeting in January 2002, our project receives much recognition as the earliest practical implementation of HL7 Version 3 in the world.

For the evaluation of the system, we carried out a questionnaire survey. Forty healthcare institutes of 47 institutes and 78 patients answered it.

The results of the questionnaire showed that 95 % of the healthcare providers regarded that the EPR network is effective for the regional communication but that only 35% of them regarded it worthy for their routine work. However, 100% of them are supportive for the system. Regarding the running cost of the system, 60 % of them think that 50,000 yen a month (about 450 dollars) or less is reasonable.

About 40 % of the patients had had worries about the security when they join the project. However, about 95 % of them understood the security level of the system by the healthcare provider's explanation. About 90% of them expected to promote the EPR network.

## Discussion

At the beginning of the project, we planed to release our products as open source software after the completion of the system development. For this reason, we developed the system with open-sourced software or systems such as Java, Linux, and PostgreSQL. However, we have noticed that EPR developers that are deeply familiar with such open-sourced software are very few and most of all EPR systems in use are produced by using Visual Basic or other Microsoft Windows based software except for Oracle RDBMS. To meet such environment, we are working for development of Windows C# version of the system.

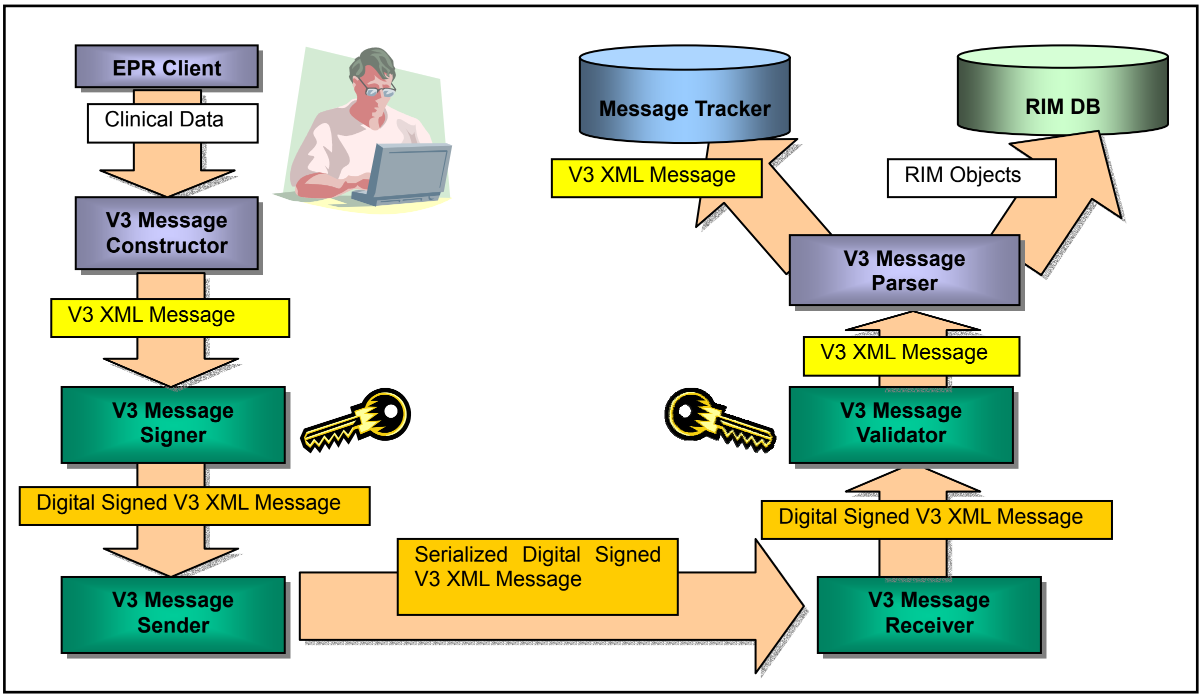


*Figure 6- System architecture*

In addition, personalized medicine or tailor-made medicine is in very near future. We are now extending the patient record system in order that it can deal with genome information.

## Conclusion

In this paper, we have described an HL7 version 3 based EPR system developed in Japan. This is the first practical healthcare information system based on HL7 Version 3.

Now we involve in a project on the development of a secure framework for healthcare message transfer and its evaluation. About one million dollar is funded by the Japanese Ministry of Economy and Industry from 2002 to 2003. In this project, we are developing a secure framework for exchanging HL7 Version 3 messages.

Another project in which we involve is "A Study on Development, Management and Distribution of HL7 messages for Electronic Patient Records". About 150 thousand dollars per year is funded by the Japanese Ministry of Health, Labour, and Welfare to this project from 2002 to 2005. In this project, we aim to develop Version 3 messages for EPRs and to develop methods to manage and distribute the messages. In addition, we also aim to develop HL7 messages that can handle genetic information as well as clinical information.

## Acknowledgments

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