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Dolphin Project—Cooperative Regional Clinical System Centered on Clinical Information Center

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In 2001, a system was created to improve patient service, improve the quality of medical care, and achieve efficient medical care. A Data Center was established to accumulate and manage clinical information in the regions and share clinical information safely and appropriately. The system has already been in operation for 3 years. Even though a patient may have been examined at multiple hospitals, his medical record information will be integrated at the Center. This ensures medical care continuity and enables the patient to view his own medical records at home. Its usefulness in obtaining informed consent has been demonstrated as well. XML instances established in the MML standards (MML (Medical Markup Language): http://www.medxml.net/E_mml30/mmlv3_E_index.htm Accessed July 2004; Jpn. J. Med. Informatics (JJMI) *17(3):203–207, 1997;* J. Med. Syst. *24(3):195–211, 2000; J. Med. Syst. 27(4):357–366, 2003;* J. Med. Syst. *28(6):523–533, 2004) are used for Electronic Medical Record System data exchange between the Data Center and each medical institution. The openness provided by XML makes it possible to connect diverse electronic medical records to the Center. As of the year 2004, over 10 types of electronic medical records have an MML interface, enabling connection to the Center.*

KEY WORDS: MML; cooperative regional clinical system; XML; informed consent; electronic medical record.

INTRODUCTION

Since the Ministry of Health, Labour, and Welfare (MHLW) issued its notice in April 1999 (approving the electronic storage of medical records), the introduction of electronic medical records at national universities, key regional hospitals, clinics,

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and other facilities has advanced. And in the past few years, that trend seems to have accelerated. It should be noted that behind this trend and in line with the e-Japan concept there has been financial support from the MHLW and Ministry of Economy, Trade, and Industry (METI). Also, according to private market surveys, Japan's electronic medical records market is expanding in a broad sense. It has even been projected to grow from the 20 billion yen level in 2002 to 160 billion yen level 5 years later. Given the ambition shown in the grand design of "Aiming for 60% diffusion within 5 years" announced by the Ministry of Welfare, expansion of the electronic medical records market has become more likely. In contrast to these positive observations, however, a satisfactory supply structure is not in place for these vital products, the electronic medical records. Moreover, the preparation of infrastructure for supporting the wider use of electronic medical records is clearly a step behind. The authors, in the FY 2001 "Regionally Shared Electronic Medical Record System Research and Development Project (METI)," submitted applications (proposed project plan) via the Miyazaki and Kumamoto regions, and fortunately the project was adopted for both regions. Thereupon, the joint development of a commonly accessible system began as the Dolphin Project.[6] Planning went forth to develop a system that allowed clinical information to be accessed safely and appropriately, while protecting privacy. To achieve this objective, a Center was established to safely accumulate and exchange electronic medical record information in the region. Through this Center, information could be shared by patients, hospitals, clinics, examination centers, and pharmacies. Even if a patient was examined at multiple medical institutions, his medical records would be integrated at the Center. Thus, a "single region, single patient, single medical record" system became a reality.

DOLPHIN PROJECT OVERVIEW

What is the Dolphin Project?

The essence of the Dolphin Project is to provide an information base that can efficiently interconnect the various clinical information systems that exist in the region. Clinical information (such as medical record data and examination data) that has been accumulated by the Center's server is shared under strict security. This allows health professionals to view, in a centralized manner, the medical records and examination results of patients who have a medical care agreement. This not only facilitates hospital-to-hospital and hospital-to-clinic cooperation but enables patients to view their own medical records and to enter symptoms and make other entries into their medical records (disclosure of electronic medical records).

To enable information sharing, a Regional Clinical Information Center (Data Center) is established and connected to facilities such as clinics, large medical institutions, and examination centers. Medical records, examination results, letters of referral, and discharge summaries are converted to XML instances in MML format and then sent to the Center for storage. This clinical information is shared throughout the region and is used by medical institutions as medical record data backup, and by authenticity verifying servers to demonstrate tamper resistance. Furthermore, through the operation of patient service portal sites[7] and user registration services,

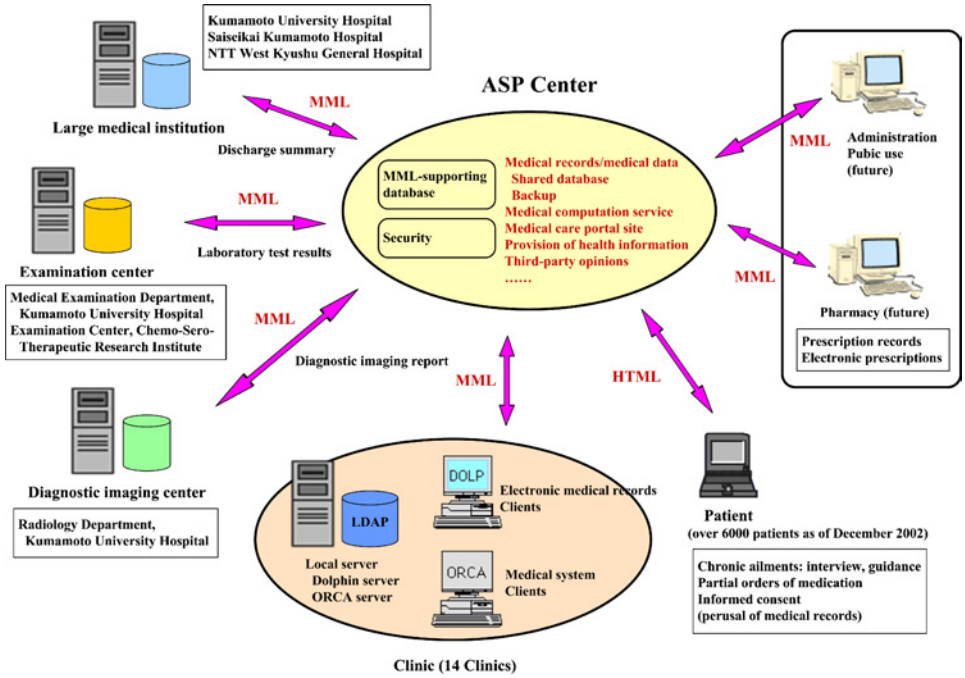

Fig. 1. Dolphin Project overview.

the Center provides various forms of support to patients who are the system's users (members). As of July 2004, the number of medical institutions connected to the system included three large medical institutions, three examination agencies, and thirteen clinics in Kumamoto Prefecture, and seven large medical institutions, six examination agencies, and forty clinics in Miyazaki Prefecture (Fig. 1).

Development of Electronic Medical Records for Clinics

To link hospitals and clinics, clinic electronic medical records (development code name "OpenDolphin" for clinics)[8] were developed. The database engine is an OpenLDAP that runs on Linux, while the client is a JAVA application that runs on Windows. Incorporated functions include medical record entries and orders (such as prescriptions and examinations), as well as appointments.

Since OpenDolphin can operate independently of the Center server, it can also be employed as an electronic medical record for exclusive use by clinics.

Connection Between Japan Medical Association Research Institute's Version of Receipt Computer (ORCA) and OpenDolphin

OpenDolphin was not equipped with a receipt computer function, and operated in combination with ORCA.[9] Orders issued from OpenDolphin are automatically transferred to ORCA as XML (CLAIM) data, and receipt processing is executed.

On the ORCA side, with the exception of patient registration, nearly all input to the receipt computer (ORCA) became unnecessary.

XML Interface

All the systems developed under this project are equipped with an XML (MML, CLAIM)[6] interface and are designed to maintain mutually open and independent relationships. The purpose is to eliminate system exclusiveness through tight coupling, and in the near future, to enable diverse electronic medical records and receipt computers to be included in this project. Through this technology, the electronic medical records used in this project will initially be limited to OpenDolphin, but other electronic medical records will be connected in the future as well. Also, ORCA will be used initially as the medical system; however, existing medical systems will also be possible to connect if they are equipped with a CLAIM interface. As of July 2004, 8–10 systems were equipped with a CLAIM interface and used by electronic medical records such as OpenDolphin or Wine Project,[12] and 3–5 systems were equipped with a receipt computer such as ORCA, Fujitsu, or NEC. Electronic medical records that are currently equipped and operating with an MML interface include OpenDolphin and Wine. Also expected to make an appearance are MML-supporting electronic medical records that are being newly sought in connection with a cooperative system of the Tokyo Medical Association (HOT Project[13]).

Center Server System

Cache[14] was adopted as the database engine. The Center's system has an MML interface and accepts the following MML instances from medical institutions to which it is connected:

1. Electronic medical record data issued from clinical electronic medical record (such as OpenDolphin).
2. Examination results issued from examination center.
3. Diagnostic imaging report issued from radiodiagnostic imaging center.
4. Discharge summary or electronic medical record data issued from key regional hospital.
5. Medical record data written directly by a patient, doctor, or pharmacist via Web electronic medical record.

After being received, XML data is analyzed and imported into the database. Upon request, it is converted to XML (MML) again and sent back.

Web Interface of Center Server

Normally, once medical record data is incorporated into an electronic medical record, it can be viewed by electronic medical record application. For users (mainly

[6]MML/CLAIM[10]: XML common standard established by MedXML consortium[11] to link electronic medical records and medical profession.

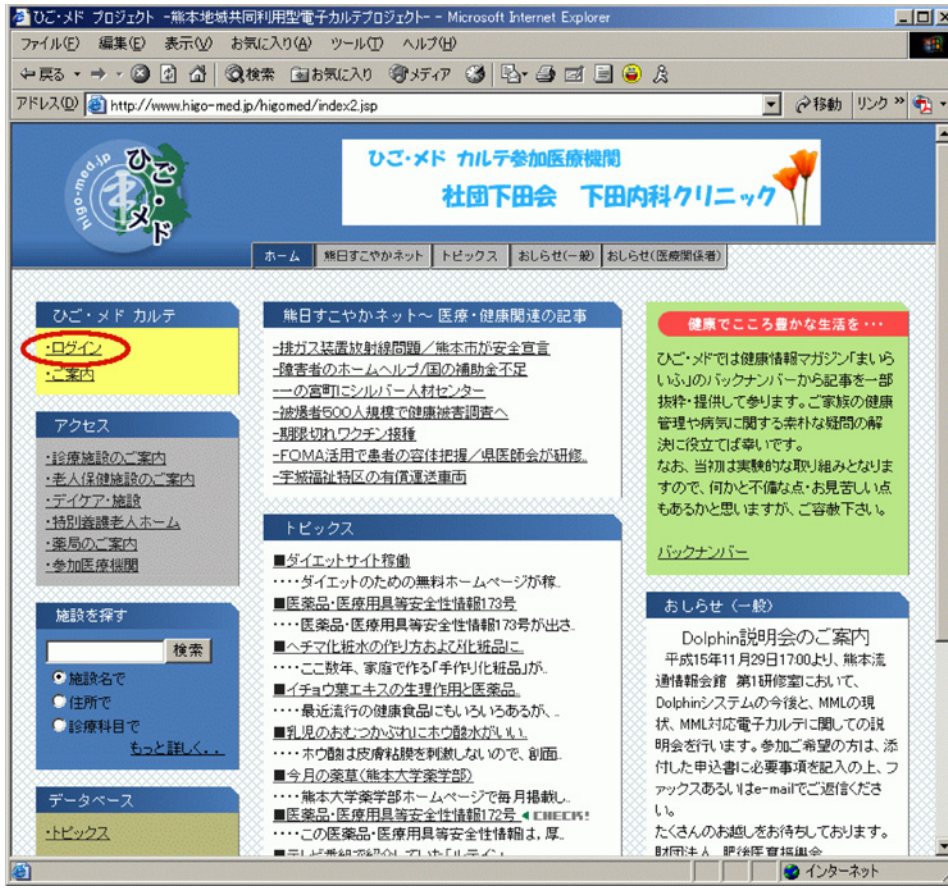

Fig. 2. Portal site operated by Kumamoto Regional Clinical Information Center.

patients) who do not have an electronic medical record system, the Center system is equipped with a Web interface that allows access by Web browser. Patients and medical institutions that do not have a system can access (read and write) electronic medical records by personal computer from their home or hospital with the feel of viewing a home page. The Kumamoto Region Dolphin Project makes it possible to log in to individual electronic medical records from a "*Higo Medo*" portal site.[7] Access requires an account, password, and electronic certificate issued by the Center (Figs 2. and 3).

Pressing the upper-left button (round red mark) logs in the user to the patient's individual medical record.

Security

By combining user authentication, network encryption, and access control, the system handles individuals' private information (medical care information) safely

Fig. 3. Web electronic medical record provided by Regional Clinical Information Center.

and appropriately. When the Center is being accessed, user authentication is executed and the channel is encrypted through SSL and VPN, making it impossible for unauthorized persons to break into the system. Also, access permissions are established for each document that is included in the medical record (such as ailment names, examination results, reports, and progress notes). Accordingly, doctors who are not involved in a patient's medical care cannot access that patient's data. In this way, regionally integrated individual medical records can be created in a manner that strictly controls whether a person is a party to a medical care agreement (single patient, single region, or single medical record).

PROBLEMS

Securing of Electronic Medical Record Diversity in Market

Now, the introduction of electronic medical records is being recognized as providing a number of important functions, such as, data sharing for cooperative medical care, service to patients, and coordination with outside groups, not simply for office automation. And in contrast to the history of ordering systems, electronic medical records are beginning to see wide usage in both large hospitals and clinics. Existing vendors are providing large hospitals with Electronic Medical Record Systems developed from the ordering system, but offerings to the clinic level have not advanced much. At large hospitals, despite an awareness that there is dissatisfaction among doctors and other users, packages are being introduced in

an attempt to use them somehow, even though the individual circumstances of the medical departments are not being taken into consideration. At clinics, on the other hand, there is a strong demand according to medical care field and that demand cannot be met with the current products of large vendors. Small vendors have been sending forth specialized products to the medical departments, but the variation still does not meet market demand. Since the target range handled by ordering and receipt computer is relatively small, if there are not more than about 10 products, any one of them can be selected. However, the target of electronic medical records is medical care itself; therefore, it is necessary to have a variation that at least covers the medical care items. Currently, doctors who are actually engaged in medical care are doubling as programmers in the development of systems, which come into use by word of mouth. This is the predominant pattern. But when sales or support comes into play, extremely awkward situations can result. In the future as well, electronic medical records will not likely be sold only by large vendors; rather, diverse electronic medical records will likely continue to be supplied by small vendors even though business may be unstable. For users, however, stable support and system continuation are important issues. To improve in this area, it is important, for instance, to develop organizations such as support centers that are jointly operated by small vendors and to secure and maintain a business environment (healthy business structure) that can continue to create systems.

Patient Identification Number

The most troubling issue faced during the Dolphin Project was the nonexistence of reliable, official patient IDs. For multiple medical institutions to be able to share clinical information, a unique patient ID is absolutely essential. For the time being, the Basic Resident Register ID (Ministry of Public Management, Home Affairs, Posts, and Telecommunications) is not expected to be used outside of administrative service. Health insurance card numbers, too, change with a career change or retirement; and since they are issued only to the head of the household, the other members of the family must be issued branch numbers. Ultimately, each medical institution's patient medical record numbers were linked to the patient IDs issued independently by the Regional Clinical Information Center. But because medical institutions had to link IDs issued by their facilities to IDs issued by the Center, this created additional work and a heavy burden to the medical institutions. There are limitations to the efforts that can be made toward this regional project by the private sector alone. To efficiently promote the development of IT in the society as symbolized by an electronic government, for example, it is hoped that "personal identification," the most basic part of the IT base at the national level, will be promoted at the administrative level or that private service having a corresponding degree of reliability will emerge.

Concept Change: To Patient-Centered Medical Care

It is a fact that streamlining on the medical institution side has been a great motivator to the medical system, ordering, and electronic medical record flow. There

was the impression that the priority for handling medical care data was on the medical institution side. However, with the experience of the next phase, that of the "linking of electronic medical records," the necessity of rethinking the concept came to be realized. The current experimental cooperative regional medical care included the task of obtaining the patients' consent to send their medical record data to the Center. The idea of "obtaining consent as a precautionary measure" came into being because there was a perception that the data was handled under the leadership of the hospital. If patients had their own accounts in a place such as an information bank where they could accumulate and manage their personal data, there would be no need to obtain "consent." That is because the patients themselves would be seeking the information. If we look carefully from the patient's point of view, it would be difficult to place our complete trust in the management of our clinical information, since storage periods and other aspects vary from hospital to hospital. That is because once the minimum period established by law has been cleared (currently 5 years), subsequent management by the hospital depends on the policies of the individual hospital. It would be better if clinical information, once generated, was promptly transferred to the individual's account, where the individual could be responsible for determining its storage period and other handling. Seeking the opinion of the third party would also be upto the discretion of the patient. Moreover, the patient's decision should be respected as to whether to allow a doctor to view past data when the patient had been examined at another medical institution.

Center System: Function and Operation

Although the basic performance is sufficiently practical, it is felt that the currently independently operating Center database should be separated into a database for medical institutions and a database for patients. Separating the database would make it possible to manage the former for business use by medical institutions (storage, authenticity), and the latter as an account for managing the patient's clinical information (perusal by patient, cooperative medical care). The latter would clarify the patient's priorities and eliminate ambiguities regarding consent to use the data, thereby making it possible to avoid needless trouble.

Operating the Cooperative Center during the past few years, we have become keenly aware of how extremely difficult it is to raise funds for operation. Medical institutions and patients will pay for things that they can see (such as electronic medical records), but hesitate to pay for services that are performed in the background, such as those of the Center. Under normal circumstances, the Center's maintenance costs would be jointly shared by the current users. At the present time, however, since the service is not in wide use, it is an extremely expensive service, making cost sharing unrealistic. Currently, regions that have implemented this type of service include Miyazaki, Kumamoto, Fukuoka, and Osaka, and will likely include Tokyo and Kyoto in the future. But it will likely be difficult for such services to be profitable if they are implemented separately through regional projects. Accordingly, a higher-level project called "Super Dolphin" is being developed for the purpose of virtually bundling these regional projects. Super Dolphin will perform the role of a super directory, providing "computer-aided name identification" of

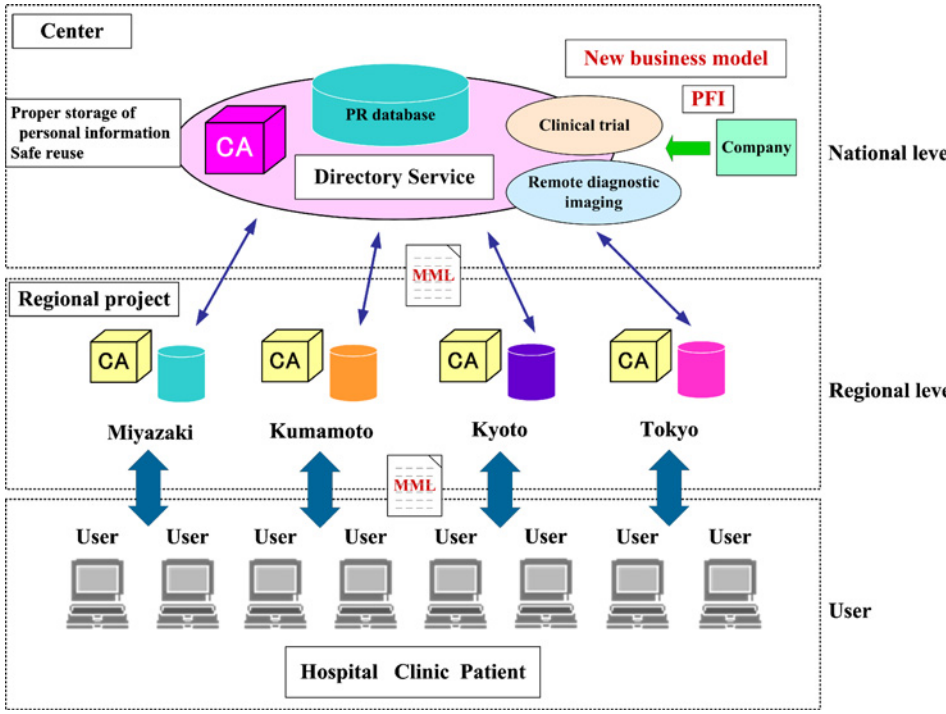

Fig. 4. Relationships between Super Dolphin, regional project, and user.

patients registered in each project. It will also lend databases to economically weak regional projects, and help start up services with minimal funding. In addition it will "manage" accumulated medical care data just like a bank, and return management gains to each project and apply them to project running costs. Super Dolphin may start up as early as FY 2004 (Fig. 4).

CONCLUSION

This report summarized our impressions and experience of developing and managing an Electronic Medical Record System for cooperative medical care. It seems as if IT-assisted medical care is tracing the history of banking but at a 15 year lag. Banks started from a centralized account system, converted to a decentralized slip input system, and later interconnected with each other, making it possible to provide depositors with wide-area mutual entry services. Medical care IT aims for "single accounts," which the financial community has not achieved. Up until now, we were satisfied to simply follow our dreams and create electronic medical records. However, that will no longer be the case. The next 5–10 years will be a crucial period in the development of medical care IT. It will likely be a period in which we must face some very difficult real-world hardships.

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