5. 安徳恭彰，中島直樹，山下隆範，山之口稔隆，
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二次利用目的で抽出する診療データの暗号化のためのパスワード管理システム

○安徳恭彰[1)]、中島直樹[1)]、山下隆範[1)]、山之口稔隆[1)]、田中雅夫[1)]

1）九州大学病院医療情報部

e-mail：antokuy@info.med.kyushu-u.ac.jp

１．【背景】

九州大学病院（以下本院）では 2008 年の電子カルテ化以降、診療情報は日々データベース上に蓄積されており、データ解析の需要は日々増大している。本院では、それらのニーズに応えるべく、システムの利便性を高めるデータベース構築等を行っている[1)]が、需要に応えることと同時に二次利用に関する危惧すべき点の検討も重大な課題となっている[2)]。

九州大学病院では、電子カルテのネットワークは、研究用をはじめとするその他インターネットには接続していない。また、USB メモリ等外部メディアの利用を禁じ、データの不用意な漏洩に備えてきた。このため、これら診療情報を研究もしくはその他二次的な目的に利用する場合、専任者が抽出したデータを CD-R や USB メモリなど外部メディアに書き込み、抽出依頼者に手渡している。しかし昨今、これら外部メディアに保存されたデータが紛失等の理由により外部に流出するといった事件の報道が後を絶たない。本院でも、過去に類似の事故が発生しており、決して他人事ではない。

そこで我々は、抽出データに対する適切なパスワード管理を開始した。十分な強度を持つパスワードによってデータファイルを暗号化し、流出や漏洩に対する対応を行ったので、紹介する。

２．【目的】

データ抽出から、依頼者がデータを受け取りファイルを開くまでの間に紛失、漏洩等が起こる危険性を考慮してパスワードによるデータ暗号化を考えた。パスワードは、基本的に第３者に推測されにくい文字列が望ましいが、それらパスワードを抽出者と依頼者の間で共有することは難しい。従来は、内線番号（数字４桁）等ある程度利用者との知識共有ができるキーワードで暗号化を行っていたが、昨今のコンピュータ技術の発達とともに、数字４桁の暗号化程度では、条件さえ整えば解読することは容易である。

そこで、適切な強度を持つパスワードを、適切な方法でデータ抽出者と依頼者間で共有することを目的としてシステムの構築をおこなった。

３．【方法】

本システムは、パスワード管理システムとして、サーバ(OpenSUSE11.2)上に、Apache2.2.13 で Web サーバを構築、データベースには MySQL5.1.51 を使用した。また、本システムを利用する際の認証サーバとしては、九州大学の全学共通 ID の LDAP サーバを利用した。システム運用の流れ図を図１に示す。九州大学では、SSOKID と呼ばれる全学共通 ID を運用している。この SSOKID を使って LDAP による本人認証を行い、認証後、データを暗号化したパスワードの閲覧をおこなう。手順としては、データ抽出者がデータ抽出後、Web サイトにアクセスし依頼者の SSOKID を入力し新規パスワードを発行する。抽出者は、発行されたパスワードを使ってデータファイルを暗号化、暗号化されたファイルをリムーバブルメディア

等に保存して依頼者に手渡す。暗号ファイルを受け取った依頼者は、Web サイトにアクセスし、SSOKID で認証、表示されたパスワードでファイルを複号化する。

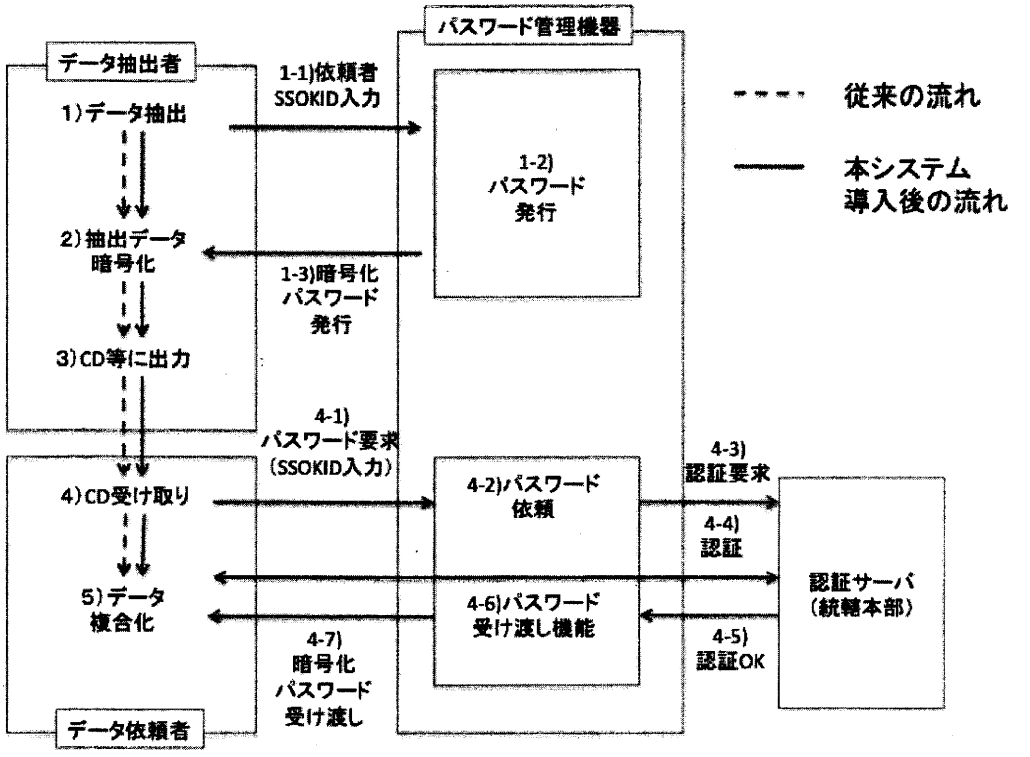

図 1　システム構成図

当初、SSOKID の ID とパスワードでの暗号化を検討したが、SSOKID のパスワードは動的に変更可能であることに対し、抽出データは抽出時に静的に暗号化される。このため、SSOKID とは独立しパスワードを管理する方式を採用し、パスワード閲覧に SSOKID による認証を用いた。

また、暗号解読の難易度を高める目的で、暗号鍵の文字列は１０文字以上とした。

4.【結果】

データ抽出者がファイルを暗号化する際のパスワード発行画面を図２に示す。データ抽出者は、SSOKID で発行画面にログイン後、依頼者の,SSOKID および付加情報を入力し、発行ボタンを押してパスワードを発行する。

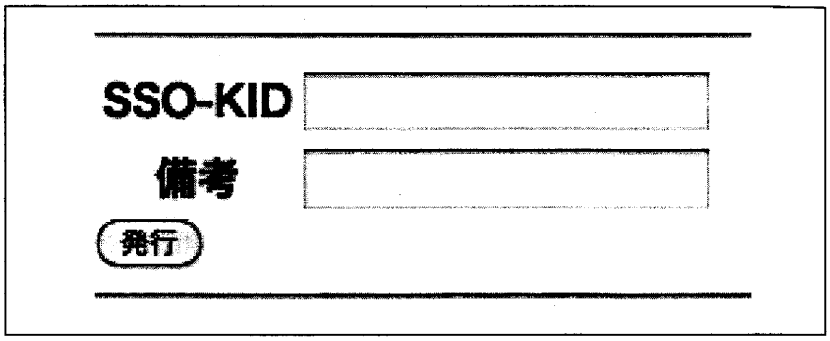

図 2　パスワード発行画面

抽出依頼者がファイルを複号化する際のパスワード確認画面を図３に示す。依頼者がログインすると、現在発行されているパスワードの一覧が表示される。付加情報を元に該当のパスワードを確認し、ファイルを複号する。

あなた（7095364168）に現在付与されているパスワードは下記の通りです。

発行日	備考	パスワード
2010-12-24 08:45:24	12月２３日情報検索用	85cxV4tL6b
2010-12-24 08:44:41	１２月２０日情報検索用	nYPrZX8Hqo

図 3　パスワード確認画面

本システム運用後の暗号を総当たりで解析する場合にかかる時間を表１に示す。解析にはフリーソフトの Zip 暗号解析ソフト Pikazip[3]を利用した。解析機器は、CPU Pentium M 1.2GHz, Memory 1GB, OS:WIndowsXP を使用した。パスワードを英小文字、数字の組み合わせと想定し、総当たりで暗号解析を行った。

表１　文字種、文字数における暗号解読にかかる時間
（検証環境：CPU Pentium M 1.2GHz, Memory 1GB, OS:Windows XP）

文字数	数字のみ	英小文字のみ	英小文字、数字
4	0 秒	0 秒	0 秒
5	0 秒	6 秒	35 秒
6	0 秒	3 分 7 秒	21 分 51 秒
7	6 秒	68 分	*13 時間程度
8	1 分 2 秒	*29 時間	*19 日程度
9	10 分 50 秒	*32 日	*1.9 年
10	*100 分	*2.26 年	*67 年

*は実測値から計算される推定値

従来の数字４桁の暗号化では、ほとんど時間をかけずに解読できたのに対し、５桁では 35 秒、６桁では２２分程度かかる結果となった。この結果を元に英数１０文字以上で行った場合を計算すると、解析にはおよそ６７年かかる。本システムは、英小文字、数字に加

え、英大文字も含んでいるため、今後、高スペックのPCによる暗号解読が行われるとしても、総当たりでの解読はほぼ不可能と考える。

また、暗号化にかかる手間としては、従来の暗号化の場合と比べ、パスワードの書き写しによる手間以外はほぼ時間の差は発生しない。

5.【考察】

電子カルテシステムと、研究用インターネットが物理的に切り離されているため、パスワード書き写し時のエラーが問題視される。これに関し、電子カルテシステム側にパスワード発行、研究用ネットワーク側に閲覧機能といった形でシステムを分散させ、何らかの形でパスワードの同期が行えれば、これらの問題は解消されるものと考える。

6.【まとめ】

診療データ抽出時の暗号化を強化するため、パスワード管理システムを構築した。大学で一斉発行している全学共通IDと連携させることで、集中的な管理を可能とした。また、従来、ある程度推測しやすいパスワードでしか暗号化できなかったものを、より強度なパスワードで暗号化することで、診療データ受け渡し時の紛失等の問題を最小限に抑えることができたと考える。

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SS-MIX: A Ministry Project to Promote Standardized Healthcare Information Exchange

M. Kimura[1]; K. Nakayasu[2]; Y. Ohshima[3]; N. Fujita[4]; N. Nakashima[5]; H. Jozaki[6]; T. Numano[7]; T. Shimizu[8]; M. Shimomura[9]; F. Sasaki[10]; T. Fujiki[11]; T. Nakashima[12]; K. Toyoda[13]; H. Hoshi[7]; T. Sakusabe[14]; Y. Naito[1]; K. Kawaguchi[1]; H. Watanabe[1]; S. Tani[1]

[1]Hamamatsu University, Hamamatsu, Japan; [2]Ministry of Health Labour and Welfare, Tokyo, Japan; [3]Shizuoka Prefecture, Shizuoka, Japan; [4]Chiba University, Chiba, Japan; [5]Kyushu University, Fukuoka, Japan; [6]Fukuroi Municipal Hospital, Fukuroi, Japan; [7]NTT Data, Tokyo, Japan; [8]SBS Information Systems, Shizuoka, Japan; [9]Fujitsu, Tokyo, Japan; [10]NEC, Tokyo, Japan; [11]Software Service, Osaka, Japan; [12]Fuji Film, Tokyo, Japan; [13]HCI, Tokyo, Japan; [14]Fujita University, Toyoake, Japan

Keywords
Standard, hospital information systems, information retrieval, electronic health records

Summary

Objectives: To promote healthcare information exchange between providers and to allow hospital information systems (HIS) export information in standardized format (HL7 and DICOM) in an environment of widespread legacy systems, which only can export data in proprietary format.

Methods: Through the Shizuoka prefecture EMR project in 2004–2005, followed by the ministry's SS-MIX project, many software products have been provided, which consist of 1) a standardized storage to receive HL7 v2.5 messages of patient demographics, prescription orders, laboratory results, and diagnostic disease in ICD-10, 2) a referral letter creation system, 3) a formatted document creation system, 4) a progress note/nursing record system, and 5) an archive/viewer to incorporate incoming healthcare data CD and allow users to view on HIS terminal. Meanwhile, other useful applications have been produced, such as adverse event reporting and clinical information retrieval. To achieve the above-mentioned objectives, these software products were created and propagated, because users can use these software products, provided that their HIS can export the above information to the standardized storage in HL7 v2.5 format.

Results: In 20 hospitals of Japan, the standardized storage has been installed and some applications have been used. As major HIS vendors are shipping HIS with HL7 export function since 2007, HIS of 594 hospitals in Japan became capable of exporting data in HL7 v2.5 format (as of March 2010).

Conclusions: In high CPOE installation rate (85% in 400+ bed hospitals), though most of them only capable of exporting data in proprietary format, prefecture and ministry projects were effective to promote healthcare information exchange between providers. The standardized storage became an infrastructure for many useful applications, and many hospitals started using them. Ministry designation of proposed healthcare standards was effective so as to allow vendors to conform their products, and users to install them.

Correspondence to:
Michio Kimura
Department of Medical Informatics
Hamamatsu University Hospital
1-20-1 Handayama
Hamamatsu 431-3192
Japan
E-mail: kimura@mi.hama-med.ac.jp

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accepted: August 29, 2010
prepublished: January 5, 2011

1. Medical Information, Interfacility Cooperation and Standardization

It is a matter of course that the purpose of the information cooperation between facilities (the cross-enterprise information exchange) is smooth continuation of the medical examination of the patient concerned [1, 2]. Recently, the role of medical facility tends to be more differentiated. The same facility cannot always provide all the diagnosis, examination, and treatment. A subsequent care, a preventive action and individual patient information extend beyond the limits of time and place. There is an increasing need for interfacility cooperation [3]. In this viewpoint, the forerunner was the fact that the need was more imperative in underpopulated areas than in large cities.

The background that made this possible by leaps and bounds in recent years is a rapid progress of information technology. Another important factor is standardization of data. In the 1980s, interfacility exchange of information became possible because of the progress of information technology. The mismatching of data surfaced. This is reflected on the fact that since the 1990s, standardization of medical information, particularly between facilities, started [4–9].

Especially in Japan, the computerized physician's order entry system (CPOE) started becoming popular in the 80s, which was before healthcare information standards were introduced. As a result, the instal-

lation rate of CPOE systems in Japan is very high (85% of hospitals with 400+ beds), though most of them still only have proprietary data export format without conforming standards. This is a big barrier to promote interfacility data exchange.

The Shizuoka Style EMR (Electronic Medical Record) Project [10] was primarily aimed to offer the information system software towards medical facilities within the prefecture, and to promote interfacility exchange of medical information. Then, the interfacility exchange was inherited as SS-MIX (Standardized Structured Medical Information eXchange) project by the Ministry of Health, Labour and Welfare, and became available nationwide [11]. However, another purpose of these projects was that hospitals should have storage, besides hospital information system databases, to accumulate this data in standard form (HL7 v2.5) to overcome the above-mentioned barrier. This data, although not comprehensive, included prescription, lab results, basic patient demographics, and disease name registration. The information storage enabled drafting/receiving of letter-of-referrals and various documents to be created. Not only that, it provided this information to many kinds of application programs.

This paper describes the two projects, especially the interfacility exchange of information, and usefulness of the standardized information storage, which resulted in high percentage of installation of HIS with standardized export function. It further debates the directivity of subsequent information cooperation.

2. The Shizuoka Style EMR Project

2.1 Components Offered and Integration

In the 2004 and 2005 fiscal years, Shizuoka prefecture spent about 500 million yen (5 million USD) for this project. In order to mainly promote cooperation between medical facilities within the prefecture, the following system was provided (as shown in ▶Fig. 1).

A Standardized Storage
Each HIS (Hospital Information System) (shown at the upper left corner of ▶Fig. 1) issues, in HL7 v2.5 format, such information as basic patient data, prescriptions, laboratory examination results, and names of diseases. The information is received initially by this standardized storage (shown in the middle).

B Referral Documents and Data CD Management System
C, D Progress Notes and Nursing Observations Recording System
E Formatted Documents Management System
F Clinical Research Database System
Various components (shown in the right of ▶Fig. 1) increase the convenience of HIS, using information stored in the storage. The components, provided with the standardized storage, include the following: an electronic CD (compact disc) letter of referral, various formatted documents, progress notes, nursing observations.

G Picture Archive and Communication System (PACS)
Unlike other information, images were well standardized by DICOM in Japan from the 90s. Therefore there was no need to include images in the standard storage. Simple web viewing PACS is provided for mainly smaller hospitals, though large hospitals already have larger PACS. In either case, PACS provides images to the above-mentioned various components.

The program product is offered free of charge to the medical facilities within the prefecture. Needless to say, hardware and installation need expenses.

If all are used, the components of the so-called description system of EMR will be assembled. But, an order entry and account management is excluded. The operation of full paperless EMR is not mandatory for application to Shizuoka prefecture project. The purpose was to provide convenience and popularize the standardized infrastructure. So, we were satisfied with introduction of the standardized storage and the letter of referral and creation of CDs to provide information for patients (shown at the upper right corner of ▶Fig. 1).

As a result, seven facilities within the prefecture have introduced this system in 2008. Some hospitals such as Numazu City Hospital use all functions. Other hospitals such as Hamamatsu University School of Medicine Hospital (hereafter Univ. Hospital) use only the standardized storage and the letter-of-referral system, plus clinical information retrieval system (F) and the PACS.

The upstream HIS always pushes the information, in HL7v2.5 form, such as the basic patient data, prescription, lab results, and disease name registration. Any HIS is connectable to standardized storage (A) if it can provide data in this form. The conformant upstream HIS venders include several companies such as Fujitsu, NEC, SBS Information System, and Software Service.

In order to realize the interfacility cooperation, it is necessary to standardize the drug code (HOT-9 [12]) and lab code (JLAC-10 [13]). Both Japanese codes are recommended also by the EMR Promotion Committee Report of the Ministry of Health [14].

2.2 Electronic Letter of Referral

To electronize information exchange between healthcare providers, these two projects electronized a letter of referral. The MERIT-9 letter-of-referral standard [15] was previously established and experimentally used. This standard was revised to conform to HL7 RIM (Reference Information Model) [16] and HL7 CDA (Clinical Document Architecture) R2 Level 2. Conforming to CDA R2 Level 2 made this document properly stored in the storage, and the contents could be reused, i.e., the referring facility's name and patient information are automatically filled-in in the reference reply letter when the doctor starts making it. The revised document format is maintained by HL7 Japan as "Referral Document Architecture", and recommended by HELICS Council. HELICS Council was founded in 2001 to establish the recommendable standards for medical information. It is a non-profit independent organization, and corresponds to the U.S. HITSP Committee. The Ministry of Health

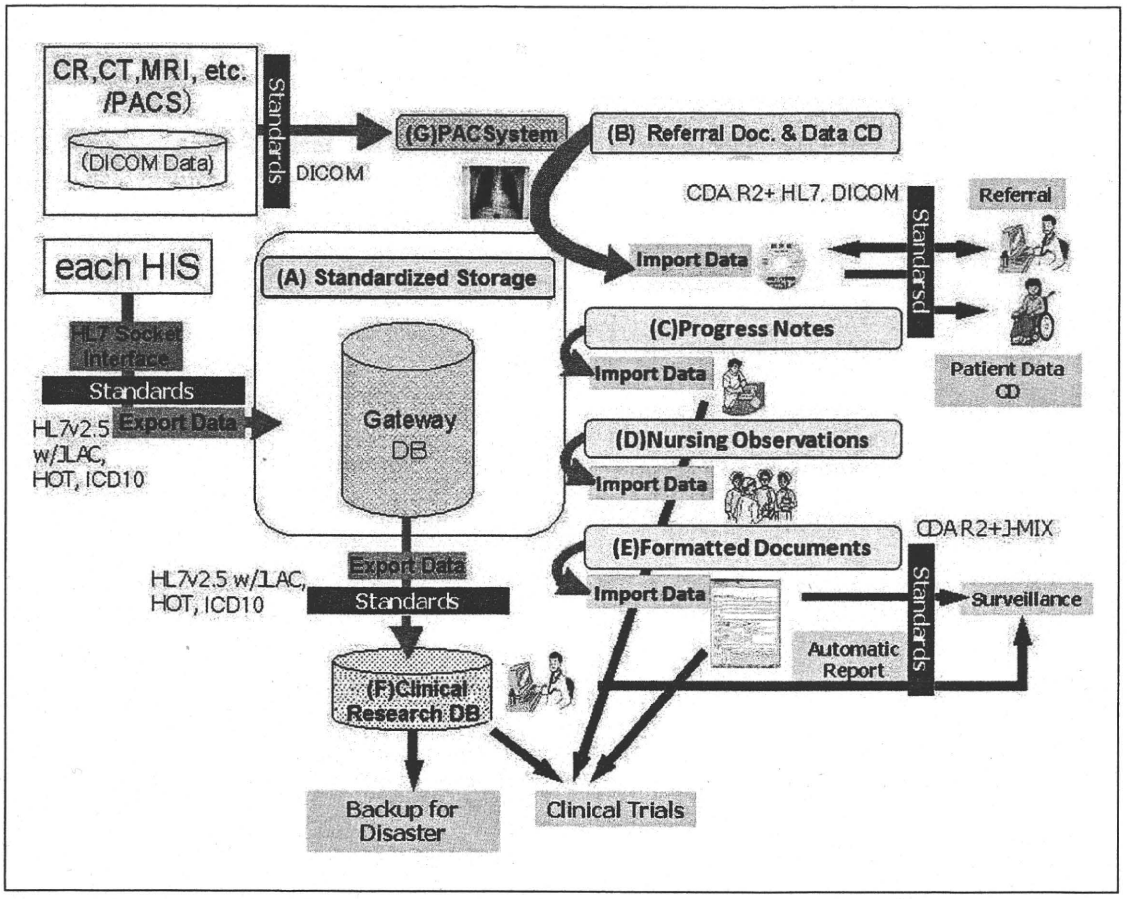

Fig. 1
Concept illustration of Shizuoka style EMR

selects the "ministry recommended standard" among HELICS recommendation, and this referral document standard became ministry-recommended in March 2010.

The revised document format consists of two parts. The first part is a CDA document that is the letter-of-referral text. The second part is an external entity in HL7v2.5 message form that includes prescriptions, laboratory examination results, and medical images conforming to DICOM Part 10 Media Storage. The storing directory structure within the CD is also defined. The viewer (▶Fig. 2) is stored in the CD. But, a receiver of letter of referral is often unable to correspond to the paperless procedures. In this case, the receiver receives a CD and a letter in paper enclosed in an envelope. Of course, a CD contains laboratory examination results, images and prescriptions.

2000 yen (20 USD) extra on the referral charge can be claimed on the basis of the nationwide medical service tariff as of 2009. If we use paper document and films for this procedure, then it is not realistic, because films easily cost more than this price. Based on the e-document law, we can charge for electronic media the same as for paper. Of course, this CD should conform to ministry-recommended standard, the Referral Document Architecture. Therefore, this extra contributed in user's preference to HIS with standardized export functions.

2.3 Patient Information Service CD

Moreover, to increase the transparency of the medical care seen from patients, participating hospitals deliver to patients, upon their request, a CD containing laboratory examination results, prescriptions, and images. Hospitals receive actual expenses. Fukuroi City Hospital had issued 110 CDs in June to November of 2008, the first year of Shizuoka project, 14 of which are by request from patients. The standard used for this purpose is almost the same as the letter-of-referral standard mentioned above. A letter of referral text is replaced by the so-called portal document, from where external links to contents of prescriptions, lab results, images are. This is also an HL7 Japan standard. It is entitled "Patient medical information and electronic medical data report standard", and recommended by the ministry. However, this electronic medical data CD is not the medical record itself. It does not contain pathology diagnosis, progress note and the name of a disease, unless a doctor writes them additionally. As for laboratory tests and images, patients obtain the same result even when they are inspected at a different facility. So, such information belongs basically to patients. As for prescription, giving printed details of prescription to patients is reimbursed, and there is no resistance. However,

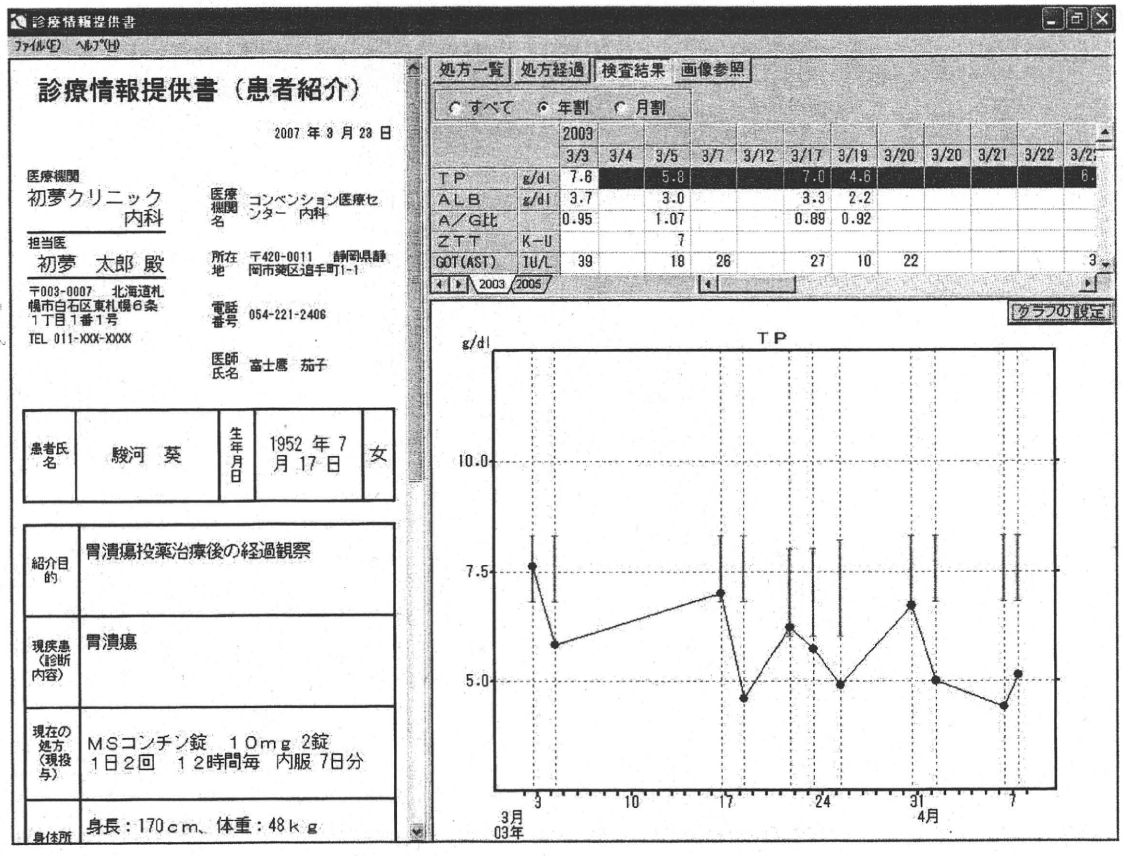

Fig. 2
Viewer screen stored in a standard. The left panel is a letter of referral. The right panel is a laboratory examination result. The two examinations shown in the middle have different range of reference values, which are clearly shown.

the names of diseases, treatment policies, etc. are also the result of the intellectual activity of healthcare providers, and patients and facilities should share them. If patients view laboratory examination result and images without being given any professional explanation, their treatment policy could be negatively affected [17]. Such data should be requested by patients to doctors, and created and distributed by mutual agreement of both parties.

2.4 Relation of IHE PDI and Shizuoka Style CD Letter of Referral

As mentioned above, images in CD conform to DICOM Part 10 "Media Storage" standard. This standard shows the directory structure in media. After that, it became IHE PDI (Portable Data for Images) profile [18] conformant. The directory structure is shown in ▶Figure 3.

When we started this project, we had another need for CD exchange of medical information. That was for medical images, even if not accompanying electronic referral documents. IHE established its PDI profile to conform to DICOM Part 10. It would be inconvenient for these two standards to be completely different between CDs with images only and CDs with images and other non-image information. So, the HL7 Japan Referral Document Architecture was implemented on CDs so that it conformed to this PDI profile. That is, we decided that the HL7 Japan Referral Document and HL7 v2.5 contents of prescription and laboratory examination result should be stored in the "other files and directories" of PDI conformant CD. As for images, the DICOM files and directory (DICOMDIR) storing part have been kept unchanged. As a result, the Shizuoka style viewer can display the PDI conforming image CD. Conversely, the usual PDI conforming viewer can display the DICOM image of a letter of referral CD.

3. Ministry Project: Standardized Structured Medical Information eXchange (SS-MIX)

The Shizuoka Style EMR project was partially inherited by the 2006 FY SS-MIX (Standardized Structured Medical Information eXchange) project by the Ministry of Health Labour and Welfare [19]. The standard storage and the electronic letter of referral software have become available nationwide. The conditions for use are the same. Any HIS, which can send various information in HL7 v2.5 message format, can use the application software as well as the standardized storage.

▶Table 1 shows CD incorporation and number of CDs created by Univ. Hospital. The incoming CD and the incorporated CD are mostly image CDs. Successful incorporation rate was 78% (607/783). The "familiar" neighboring hospitals that usually send image CDs comply correctly with PDI or a letter-of-referral standard.

But, ▶Table 1 shows that there are not few CDs that cannot be incorporated. Most of the case, they came from smaller hospitals or clinics. Most of them are DICOM files, but they do not conform to DICOM Part 10 Media Storage. (Directory "DICOMDIR" doesn't exist, or is not at proper position in CD.) Sometime, CD had only JPEG files. JPEG files do not contain any information about the examination date and time, a name of patient, and exposure parameters. Therefore, the Ministry does not recommend JPEG images for interfacility exchange of healthcare information. Some complicated cases were found when image CDs were created by connecting old DICOM complying imaging modalities with new PACS. It was because some new element repertoire was not existing in old DICOM. For example, modality type MG for mammography was newly introduced, where old PACS sorted mammography studies in XP, which is for regular plain X-rays. This has led to users complaining that they cannot find all the mammography study with the search key MG.

In Japan, patients have the right to access any healthcare facility freely; this is called the "free access" policy. In this situation, visit reservation is not necessary, which means healthcare providers cannot prepare information for patients, i.e., fetching patient information in advance. Therefore, if patients bring an image (IHE PDI) or CD of a laboratory examination result and a letter of referral to a hospital, they may present the CD at the outpatient clinic or a ward. However, the CD has not been able to be read in most such cases. This is because most HIS prohibits implementation of program (viewer) coming from outside of a hospital. A lesson learned from Shizuoka Style project was that attaching just a viewer is not enough, and that the workflow should be considered to receive information coming from outside without reservation. For example, the incoming CD should be received by a hospital/clinic liaison room without causing confusion at busy outpatient clinic. The data should be processed by that group and be displayed by web access from the HIS terminal. Such "archive/viewer" was produced by SS-MIX project to solve this problem. These products are available from SS-MIX Promotion Consortium [19].

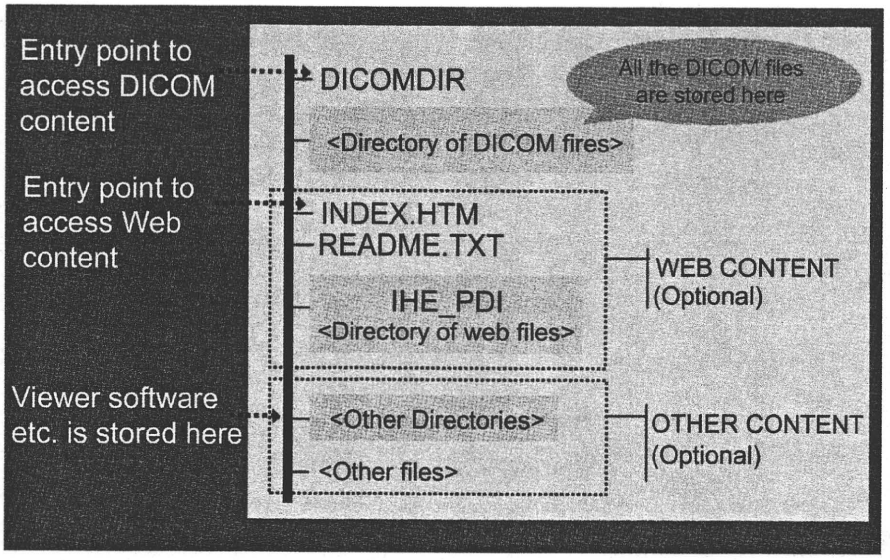

Fig. 3 Directory structure of IHE PDI profile

4. The Result of the Shizuoka Style EMR Project and the Ministry SS-MIX Project

As a result of these two projects, seven hospitals in Shizuoka Prefecture have electronized letter of referrals and attachments of information as a routine use. More than 20 hospitals have SS-MIX standard storage.

Firstly, the initial purpose was interregional cooperation. In the preliminary study implementation, Fukuroi City Hospital created 110 CDs for a half year from June through November 2008. Of course, they contain the laboratory examination result, prescription, and when required, images. Various problems surfaced through this operation. The problems include the following. How does a hospital/clinic liaison room handle CDs without allowing patients to present CDs at the outpatient clinic? The solution was in producing the archive-viewer in the SS-MIX project.

Recently, CT and MRI produce image data of a very large number of slices. How can such data be handled? As for the image, it was an example of early usual operation of IHE PDI, and the experience was reported [19]. As a result, considering the successful incorporation rate of 78% in the university hospital (▶Table 1), Japan Association for Medical Informatics recommended that the relevant academies and organizations should follow the guidelines (such as conformity to PDI, limitation of CDs to a reasonable number of images, one CD for one patient, etc.).

These SS-MIX products are used in several facilities. Kyushu University collaborates with the aged people medical checkup data and applies it to the lifestyle guidance use. Chiba University has the data accumulated for the past 20 years and use CDs to share the data with local medical facilities.

Secondly, another purpose of the project series is to popularize such function that HIS provides the basic medical information in the standard format. Fortunately, we were supported by the Ministry of Economy, Trade and Industry's "Medical Information System Compatibility Project", which was then under way. Many major venders understood the project and implemented this function to the following models.

- Fujitsu: all GX series models. As for FX series, the function is added by periodic update.
- NEC: all HR series models. As for order-made products, the function is implemented for AD v.4 or later.
- SBS Information System: all DoctorX models
- Software Service Inc.: all e-KARTE models

Table 1 CD incorporation and number of CDs created by Univ. Hospital

	Number of incoming CDs	Incorporation was possible	Letter-of-referral CDs
2008.05	34	25	
2008.06	74	50	
2008.07	76	64	
2008.08	68	56	
2008.09	76	54	
2008.10	89	65	3
2008.11	101	76	32
2008.12	97	75	24
2009.01	74	62	38
2009.02	94	80	46
Total	**783**	**607**	
Incorporation rate		**78%**	

Several years passed after the above-mentioned models were shipped. As a result, HIS of 594 hospitals in Japan became capable of exporting data in HL7 v2.5 format(as of March 2010). Total number of hospitals (healthcare providers with 20+ beds) in Japan is 8794, and hospitals with more than 400 beds is 834, as of 2008. These hospitals can use softwares, which SS-MIX Consortium provides, such as the standard storage, the function to create a letter of referral and electronic medical data, and an archive/viewer, which receives CDs, and displays it in the in-hospital server. The standard storage serves as a base to use the various derived applications described in the following chapter.

5. Various Applications Based on SS-MIX Standardized Storage

Many applications making use of information stored in the standard storage were realized. The following are some examples. Such applications made hospitals motivated to install SS-MIX-provided components.

5.1 Various Document Systems, especially for Creation of Medical Certificate for Insurance Company

Formatted document systems exist in the concept of Shizuoka Style shown as (G) in ▶Figure 1. Initially, it was intended to assist creation of prefectural documents such as the specified diseases of special reimbursement, etc. Various document systems select the existing data from the standardized storage, put the data into the document template automatically or semiautomatically after selection. The remaining part is filled by an author. Preparing medical certificates for insurance companies is the most popular among users of SS-MIX storage.

We measured writing time with and without this formatted document system, to prepare certificates for insurance company. Average time without this system was 16 minutes 1 second, with this system was 10 minutes 11 seconds (each 9, total 18 documents, by 3 doctors)

5.2 Post-marketing Drug Adverse Event Report

The post-marketing drug adverse event report requires prescription details of not only the targeted drug, also the concurrent drug. Details of laboratory examination results are also required. These are what standard storage supplies. Doctors only have to fill the pages for findings of the adverse event. A report creation system used at Univ. Hospital [21] conforms to one of IHE profiles RFD (Request Form for Data Capture) as form filler, though proven only as preliminary implementation, because no counterpart of RFD was found at Connect-a-thon in Japan until 2009. A half of major hospitals in Japan could easily build the infrastructure (standardized storage) that can use this system. Now, it is the turn for drug companies. They are required to build an analysis system that performs a quick analysis and detects adverse events as early as possible.

5.3 High-speed Clinical Data Retrieval System: D*D

This system is shown in ▶Figure 1 Concept Illustration of Shizuoka Style EMR as (F). Univ. Hospital has accumulated medical data since two-generation HIS ago for the past 10 years. Thus, 73,709,298 pieces of information have been obtained and collected in HL7 form. The Cache database was used to enable high-speed data retrieval system, D*D [22]. This retrieval system is featured with its capability of time-sequence retrieval of the subevent within a specifiable period after the occurrence of the main event. An example is as follows. Pravastatin (Mevalotin) (either 5 mg or 10 mg, including other generic drugs) was prescribed, and within two weeks, recorded Aspartate Amino Transferase (AST) > 150. The result was 83 patients. The search time was 112 seconds. Time-sequence search is the most important to find causal relationship, and without the time-sequence, a search for just an intersection of Pravastatin prescription and AST > 150 resulted in 330 patients in 4.8 seconds. The specifications of the hardware used are as follows; Database: Cache ver 5.0, CPU: Intel Xeon (3.2 GHz) CPUx2, main memory of 3 GB with database cash 1,280 MB, 10 years of data are stored in 35 GB of HDD.

Another function enables us to preset the search condition, to let the system search every night automatically and e-

mail the result. An example is like TS-1 or Panaldine administered to patients with low WBC (white blood cell), low lymphocyte and low liver function. Pharmacy is referring to the ward concerned instantly in the next morning.

Furuta reported: "The phenotype of CYP2C19 influences greatly the PPI (Proton Pump Inhibitor) effectiveness of the patient of reflux esophagitis"[23]. He found the relation with PPI in less than one hour, because he was able to easily check the relation with many prescriptions and lab results. This is thanks to standard accumulation of all lab results and prescriptions [24].

5.4 Information Service to Each Department System in Hospital

HIS staff receives a request from each department that HIS should provide basic patient data, laboratory examination results, etc. to the department where the information system was introduced. If HIS staff meets the individual request separately, then HIS will become too inconsistent to be maintained properly. If HIS is to be transferred, then extra work will be needed. Univ. Hospital encourages each department to pick up from the standardized storage. Examples of them comprise of the chemical laboratory department system, pharmacy department system, etc. One of the remarkable interconnections is with the anesthesia ledger system called JSA2006 by the Japanese Society of Anesthesiologists, which is designed to import HL7 v2.5 messages.

6. Discussion

6.1 CD Operation and Privacy

The information cooperation between facilities with Shizuoka Style was realized by using CD as a base. We did not use a network partly because the society does not yet recognize its safety. The Shizuoka prefecture people were polled last year about how their medical information should be handled [25]. They were asked whether it is problematical that patients' medical record is browsed only by themselves on the Internet. The 12.2% and 11.8% of pollees answered somewhat yes and positively yes, respectively. Unless this problem is solved, there is resistance against browsing on the Internet, even if it is technically safe [26].

We use a portable medium because presentation of the medium means the consent that a receiving medical facility is allowed to see the information contained in the medium. In Japan, right of free access to any healthcare facility means that a patient even doesn't have to present a written letter of referral and a CD to the referred hospitals.

We recognize risks of CD loss by patients. Basic policy in these two projects is that CD is the copy of information in hospitals, which are mandated to keep the medical records as original records. This is applied to both CDs, referral document CD and patient service CD. The risk of privacy violation caused by loss by patient is thought as a responsibility of the patient, just as paper-printed information. Patients are asked if they want encryption on the media.

We used a write-once CD (CD-R) instead of a recordable CD (CD-RW), because a recordable medium is not stable. Even so, CD-R is not always free from falsification. To falsify information, anyone can copy data to a new CD, add some false data, and throw away the original CD. To prevent falsification, digital signature will be needed from now on. HL7 Japan designates 128 bit block cipher of one key crypt system as encryption technique to be used [27]. Digital signature is to be done by each doctor with his or her own key, when a doctor issues an order to create a referral CD.

6.2 Information Exchange among Multiple Facilities

6.2.1 IHE XDS vs. CD-based Information Exchange

XDS (Cross-enterprise Document Sharing) is a profile of IHE IT Infrastructure for data exchange among healthcare facilities and is well used worldwide[28]. In Japan, a pilot implementation study was employed for stroke patient information sharing in the Nagoya area [29]. Two of the reasons why we used CD-based information exchange are about recognition of safety for network transfer and implicit consent to allow receiving doctors to view the contents, as mentioned in the preceding section.

If we could have started from the beginning of the design of IT system in each facility, XDS was the best choice because it was already well tested and proven efficient. In Japan, however, CPOE installation rate was already high, though most of them only can export information in proprietary format. There are two steps to realize semantic interoperability. The first one is to standardize the contents to be exchanged. The second one is to standardize the exchange protocols. The first step takes five or six years considering the replacement cycle of HIS, while the second step can be implemented in much shorter years by, for example, government policy. We started from the first step, showing many useful applications to motivate hospital decision makers. SS-MIX standard storage is a fine infrastructure for each facility to make documents to be shared with other facilities with XDS. In fact, in spring of 2010, Ministry of Health called for proposals to Regional Healthcare Reform Funds (total 290 billion yen = 2.9 billion US$), where many regional proposals are based on IHE XDS framework with documents made on the SS-MIX standard storage.

6.2.2 Semantic Interoperability with Standardized Codes

When information is exchanged between two facilities, if a human receiver reads paper documents or views film images, standardization of medical information is not needed. When information is put into a database, standardization is needed at several levels. In addition to the data grammar such as HL7, mutual agreement of an item code, etc. is needed. Moreover, when information is exchanged among multiple facilities, for example, in multidisciplinary data collection, standardization of unit system or reference value, for example, of lab results is needed.

The viewer in ▶Figure 2 indicates a bracket of reference value on a lab tests graph. A different reference value within

HL7 message is indicated with a different bracket in different dates. This technique handles interfacility difference in the disciplinary study. In Japan, proprietary item codes, as well as proprietary data export message format, are spread widely. Feature shown in ▶Figure 2 is only realized because SS-MIX standard storage requires JLAC-10 for laboratory examination code. Promotion of SS-MIX standard storage also means promotion of standard codes. With the designation of ministry standard (HOT-9 and JLAC-10 are also designated), Regional Healthcare Reform Funds from the ministry is a very good opportunity of making standard codes to be used in Japan. As with the case of various document systems, a collector should send, to many filling hospitals, the document form in XML schema together with style sheet. This is to make interdisciplinary study more efficient and to limit the data type in addition to the data column.

6.3 Comparison with Medical Information Cooperation in Other Countries

There are many EHR projects among the world. Some are regional, and others are national such as in Canada [30], United Kingdom [31], Taiwan [32], and Korea [33]. Every project considers standardization. The scope of cooperation does not cover all clinical information, but is limited to specific use case (for example, an electronic prescription [30, 34], the essential document at the time of disaster [32], etc.). The reasons are as follows. A comprehensive project needs many medical professionals, equipment, education and incentives. Besides, it is difficult to maintain the information context constant among participants.

Some clinical fields strictly specify the definition of term description in clinical protocol. Others do not. It is difficult to unify the granularity of information to be sought.

▶Figure 4 shows several use cases of information exchange and its composing information. Even for the same "neurological condition" column, for example, the information granularity is different between the common home care and the very rare specified disease registration requiring professional information. However, the granularity will remain almost the same for prescription description, chemical laboratory examination for all of these use cases.

We have to wait for the ontology study in order to correctly handle the context difference behind the same language expression [35]. For the time being, as revealed in this study, if each department shares the common basic data, then we can benefit much from many applications. Current level of common basis is shown as the bold bar in ▶Figure 4.

To achieve semantic interoperability, standardization is required from the bottom layer (transfer protocol) to the top layer (semantic contents description). It is impossible to accomplish all levels at one moment, as technology development speeds are different between layers. Japan's challenge has been that widespread CPOE had proprietary information export message format and proprietary item codes. In any situation, it is important to define the common basic level for infrastructure, where many useful applications can be built on.

7. Conclusion

Though, in Japan, CPOE installation rate is very high, most of them are only capable of export information in proprietary message format with proprietary item codes for drugs and laboratory examination. To overcome this barrier to accomplish semantic interoperability between healthcare facilities, we started the Shizuoka Style EMR and Ministry's SS-MIX project, which promote standardized information storage to be used for making referral document CDs, clinical information retrieval, etc. These projects were successfully resulted that 594 hospitals in Japan became capable of exporting data in HL7 format.

In these infrastructures, many other applications are being developed and used, not only for interfacility exchange of information, so that their products may be shared (in other words, with the market scale feasible for commercial introduction). To make it happen, defining the stable target level of standardization, con-

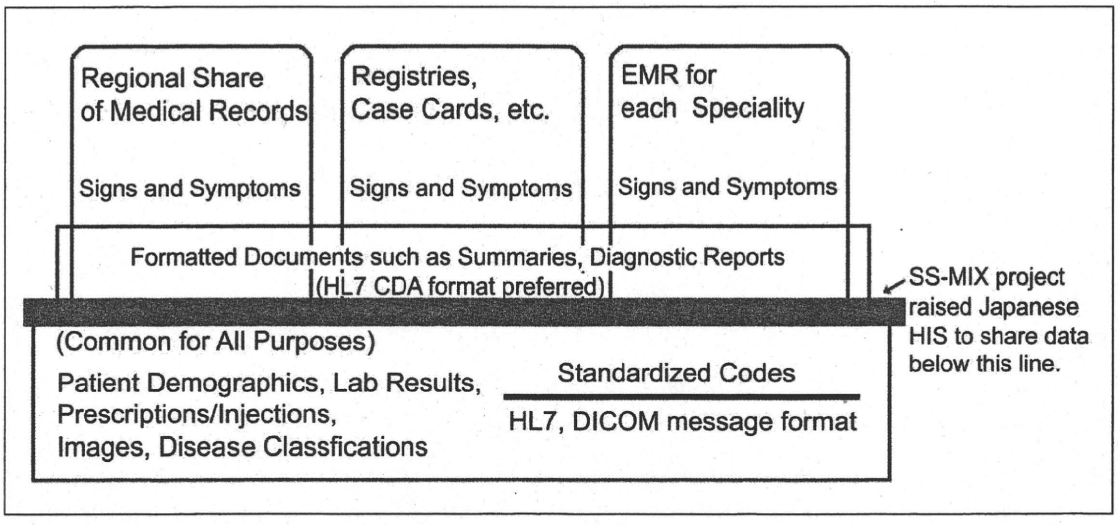

Fig. 4 Granularity of medical-examination information. The thick line shows the minimum agreement level required by Shizuoka style and SS-MIX.

sidering the challenges each situation may face, which should be coherent with private sector development and government leading policy, has been proven to be important.

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7. M. Kimura, A. Endo:
MIHARI Project-
PMDA's Pharmacovigilance
project with information
out of Japan's HIS
CDISC interchange Japan,
Tokyo, July 21, 2010.

CDISC JAPAN INTERCHANGE SESSION DETAILS

TUESDAY, 20 JULY 2010

(Interchange Conference, Cosmos hall, 3rd Floor)

(Japanese-English simultaneous interpretation is available)

09:00 - 17:00 **Registration**

09:30 - 17:30 **Exhibition Open (6th Floor)**

09:30 - 10:30 **Session 1:**
Welcome & Keynote
Chair: Yoshio Tsukada / J3C Chair

- **Welcome to the 2010 CDISC Japan Interchange**
  Yoshio Tsukada / J3C Chair
- **State of the CDISC Union**
  Rebecca Kush / CDISC President & CEO
- **Keynote Speech**
  Key Factors for Development of Clinical Research in Japan – Potential of Introduction of National ID System (* Under Discussion) -
  Shinichi Nozaki / Counselor Office of Health and Welfare for Director-General for Policy Planning and Evaluation, MHLW
- **Keynote Speech**
  Recent trend of Clinical Trials and Clinical Researches – Interim review of "new 5 yearly clinical trial activation plan" -
  Yuta Nakaya / Office of Clinical Trial Promotion, Research and Development Division, Health Policy Bureau, MHLW

10:30 - 11:00 Coffee break

11:00 - 12:30 **Session 2:**
CDISC Regional Update
Chair: Hiroshi Azuma / J3C Vice Chair

- **CDISC Europe**
  Pierre-Yves Lastic / E3C Chair
- **CDISC Korea**
  Sukil Kim / K3C Chair
- **CDISC Japan**
  Kiyoteru Takenouchi / J3C Past Chair

12:30 - 13:30 Lunch break

13:30 - 15:00 **Session 3:**
CDISC Standards Update
Chair: Kiyoteru Takenouchi / J3C Past Chair

- **CDISC Standards: Current & Future**
  Rebecca Kush / CDISC President & CEO
- **CDISC SHARE: The CDISC metadata repository**
  Gary Walker / Quintiles
- **Integrating Business Processes between Healthcare and Research**
  Landen Bain / CDISC

15:00 - 15:30 Coffee break

15:30 - 17:00 **Session 4:**
Integration of Standards and Processes
Chair: Motohide Nishi / J3C

- **Disease-specific Data Standards: Case Studies in TB, Cardiology and Neurology**
  Bron Kisler / CDISC Director
- **Define.XML –It's Not just for Submissions Any More**
  Joel Hoffman / Phase Forward
- **Introduction about our activities on diffusion and implementation of CDISC standards in Translational Research Informatics Center**
  Kotone Matsuyama / TRI Center

18:00 - 20:00 **Evening Reception**

WEDNESDAY, 21 JULY 2010

(Interchange Conference, Cosmos hall, 3rd Floor)
(Japanese-English simultaneous interpretation is available)

09:00 - 17:00 **Exhibition Open**

09:00 - 10:45 **Session 5:**
Safety Data and CDISC
Chair: Yutaka Sugihara / J3C

- **Using CDASH data collection forms for automated SAE reporting**
  Andrew Newbigging / Medidata Solutions Worldwide
- **Doing more with SDTM – Safety Signal Detection on Clinical Trial Data**
  Robbert P. van Manen / Phase Forward
- **E2B Under the Umbrella of HL7 and BRIDG: Looking to the future of data integrations between Pharmacovigilance (E2B) and Clinical Trial Management**
  Joerge Dillert / Phase Forward Europe
- **MIHARI Project – PMDA's Pharmacovigilance project with information out of Japan's HIS**
  Michio Kimura / Hamamatsu University School of Medicine, Ayumi Endo / Pharmaceuticals and Medical Devices Agency

10:45 - 11:15 Coffee break

11:15 - 12:45 **Session 6:**
CDISC - Current Practice & Future in Japan
Chair: Toshiaki Ogawa / J3C

- **Neotor Project: A real academic clinical trial using CDISC ODM-based EDC**
  Takahiro Kiuchi / UMIN Center
- **Remoted-SDV using electronic regional medical network system**
  Akimasa Yamatani / National Hospital Organization Kanazawa Medical Center
- **Industry Effort for Implementation of CDISC in Japan**
  Yoshiko Terui / JPMA

12:45 - 13:45 Lunch break

13:45 - 15:15 **Session 7:**
CDISC More in Japan
Chair: Hisao Iizuka / J3C

- **Activities on CJUG CDASH**
  Kazuki Furuno / CJUG CDASH Team, Mochida
- **CJUG Activities on SDTM implementation team**
  Yoshiteru Chiba / CJUG SDTM team, UMIN Center
- **Activities on CJUG ADaM**
  Hiroki Takagi / CJUG ADaM Team, Sanofi-Aventis

15:15 - 15:45 Coffee break

15:45 - 16:45 **Session 8:**
Vendor Applications and Tools
Chair: Kenji Nagaya / J3C

- **Cloud based Clinical Trial Management Systems (CTMS)**
  Chris Merriam-Leith / Transgenic Software
- **Simplifying trial data extraction with CDISC ODM as web service interface**
  Herve Ouambo Fotso / Phase Forward Europe

16:45 - 17:00 **Closing Address**
Hiroshi Azuma / J3C Vice Chair

MIHARI Project – PMDA's Pharmacovigilance project with information out of Japan's HIS

Michio Kimura
Hamamatsu University School of Medicine,
Ayumi Endo
Pharmaceuticals and Medical Devices Agency

Healthcare in Japan

- Healthcare cost: 8% of GDP
- Rated among top by WHO
- 9,000 hospitals and 90,000 Clinics
  - Average outpatient session: 3 to 5 minutes
- All residents are covered by some insurance
- Free access: patient can go to any provider
- Fee for service basis
  - Regardless of type of the insurance, service rates are fixed by MHLW, which is very low
  - DPC (Japanese DRG-PPS) has installed in large hospitals since 2006.
- CPOE: 60% in hospitals (90% in 400+beds)
- EMR: 30% in hospitals, 10% in clinics.

MIHARI Project

Medical Information from Healthcare providers for Assessment of Risk, Initiative

検討会:電子診療情報等の安全対策への活用に関する検討会
A study group for application of electronic healthcare information to pharmacovigilance

座長:開原成允 国際医療福祉大学 大学院長
Chair: Prof. Shigekoto Kaihara, Dean, International University of Health and Welfare

設置:H21年7月、5年計画
Five year project from July 2009

Motivations

- MHLW sentenced "responsible" for exclusion of HCV contaminated coagulants is a slow process, and "ordered" to improve information collection process
- MHLW's advisory concluded in making better use of electronic healthcare information (reimbursement claims and HIS)
- PMDA's project according to this.

4 WGs for each information source

- Reimbursement claims and DPC(DRG)
- Hospital information system
- Spontaneous adverse events reported to PMDA
- Post market surveillance collected by pharma co.

National project SS-MIX: HL7 standardized clinical information storage

to be used as a basis of HIS WG