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Development of the Clinical Specimen Information Management System for Multicenter Clinical Studies

Katsuki OKADA[a,b,1], Kento SUGIMOTO[a], Shoya WADA[a,b,c], Shozo KONISHI[a], Shirou MANABE[a,b,c], Yasushi MATSUMURA[a,d] and Toshihiro TAKEDA[a,b]
[a] *Department of Medical Informatics, Osaka University Graduate School of Medicine, Osaka, Japan*
[b] *Division of Fostering Required Medical Human Resources, Center for Infectious Disease Education and Research, Osaka University (CiDER), Osaka, Japan*
[c] *Department of Transformative System for Medical Information, Osaka University Graduate School of Medicine, Osaka, Japan*
[d] *National Hospital Organization Osaka National Hospital, Osaka, Japan*
ORCiD ID: Katsuki Okada https://orcid.org/0000-0002-1725-781X

Abstract. Some multicenter clinical studies require the acquisition of clinical specimens from patients, and the centralized management and analysis of clinical specimens at a research institution. In such cases, it is necessary to manage clinical specimens with anonymized patient information. In addition, clinical specimens need to be managed in connection with clinical information in clinical studies. In this study, we have developed a clinical specimen information management system that works with electronic data capture system for efficient specimen information management and the system workflow has verified at Osaka University Hospital. In addition, by combining this system with medical image collection system that we have developed previously, the integrated management of clinical information, medical image, and clinical specimen information will become possible. This specimen information management system may be expected to provide the platform for integrated analysis utilizing clinical information, medical image, and data from clinical specimens in multicenter clinical studies.

Keywords. Sample management, multicenter clinical study

1. Introduction

In multicenter clinical studies, there are some clinical studies that require the acquisition of clinical specimens, such as pathology tissue and blood, from patients, and the centralized management and analysis of clinical specimens at a specific research institution [1]. In such cases, clinical specimens will be sent to other institutions, and therefore, it is necessary to manage clinical specimens with anonymized patient information. In addition, clinical specimens need to be managed by linking the subject ID and clinical information collected in clinical studies. However, it is difficult to efficiently manage clinical specimens linking clinical information only by anonymizing patient information.

[1] Corresponding Author: Katsuki OKADA, email: katsuki@hp-info.med.osaka-u.ac.jp.

Clinical information is often collected in electronic data capture (EDC) system [2]. Generally, in EDC systems, patient ID is replaced by subject ID for anonymization management and for efficient clinical specimen management, clinical specimens are also anonymized using the same subject ID. We have developed an EDC system named CDCS (Clinical Data Collecting System) that collects clinical information in cooperation with electronic medical records (EMRs) [3,4]. In this EDC system, the doctors in each medical institution enter clinical information via template of EDC system which can retrieve the data recorded in the EMR. The EDC site server anonymizes the patients ID and issues a subject ID in each clinical study and maps input data to the operational data model (ODM) developed by Clinical Data Interchange Standard Consortium (CDISC) and sends to the EDC center server in the research institute.

In the present study, we have developed a clinical specimen information management system that works with our EDC system. In this clinical specimen information management system, clinical specimens are automatically anonymized and linked to subject ID in each clinical study in conjunction with the EDC system.

2. Methods

2.1. System Overview

This clinical specimen information management system consists of a site server to be set up in each medical institution and a center server in research institute that collects data from each medical institution. The site server and center server of this system are set up in conjunction with the site server and center server of the EDC system, respectively. The site server of this system obtains the patient ID and subject ID in each clinical study from the EDC site server and generates IDs for specimen management linked to the subject ID. Clinical specimens collected at each institution are shipped to the research institute with labels containing ID information for specimen management issued by the site server. The subject ID and IDs for specimen management are sent to the center server of this system, and together with the clinical information collected on the central server of the EDC system, are used for specimen analyses and management at the research institute. Push data transmission from the site server to the center server occurs after the data has been registered with the site server. The connection between each medical institution and the research institute is provided using a virtual private network (VPN) internet connection (Figure 1).

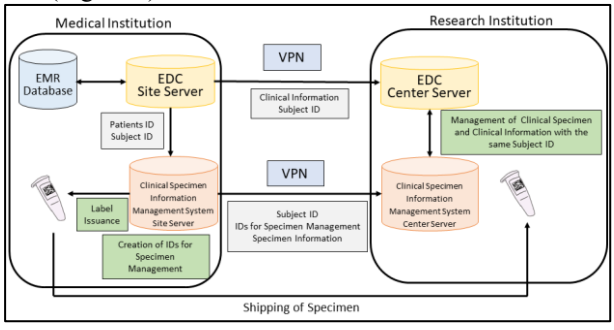

Figure 1. System Overview.

2.2. Information managed in the clinical specimen information management system

This clinical specimen information management system is a system that centralizes the management of clinical specimens generated from patients at multiple medical institutions in clinical studies. In using this system for clinical studies, a project corresponding to each clinical study is created in the system. For each project, the type of clinical specimens to be collected (serum specimens, pathology specimens, etc.) and the timing of collection (preoperative, at the time of hospitalization, etc.) are set and managed. In addition, it is possible to manage information on the location of clinical specimens' storage and the amount of specimens remaining in this system.

2.3. IDs used in the clinical specimen information management system

In this system, research patient ID, project patient ID, clinical specimen ID, and subject ID are used to link and manage clinical specimens with clinical information collected in clinical studies with EDC system (Figure 2).

Research Patient ID	Project Patient ID	Subject ID	Clinical Specimen ID
A$&00#	CAROU001	AA-0001	1CAROU0010111
			1CAROU0010231
	VSTOU015	AB-0005	1VSTOU0150221
			1VSTOU0150131

Figure 2. IDs in the clinical specimen information management system.

2.3.1. Research patient ID

It is composed of patient ID at each medical institution that are converted and anonymized by specific rules and combined with a facility code. Since a patient may be enrolled in several clinical studies, it is used to recognize that the sample is from the same patient across studies in this system. Patient ID at each medical institution, which are the source for creation of research patient ID, are automatically collected in conjunction with the EDC site server, and only anonymized research patient ID is collected on the center server; patient ID is not collected.

2.3.2. Project patient ID

Project patient ID is used to identify patients within the project created in the clinical specimen information management system in correspondence with each clinical study in the EDC system.

2.3.3. Subject ID

Subject ID is issued by the EDC system for each clinical study and automatically collected in conjunction with the site server of EDC system. It is used to link clinical specimens with clinical information collected by the EDC system.

2.3.4. Clinical specimen ID

Clinical specimen ID is issued when specimens are registered on the site server of this system. This ID is used to identify and manage the collected clinical specimens. It

contains information of project patient ID, the type of clinical specimens and the timing of collection. Clinical specimens are managed by attaching labels with clinical specimen ID information.

3. Results

3.1. Verification of clinical specimen information management system workflow

We have set up the system at Osaka University Hospital and verified the workflow of the system using 113 pathology specimens. Clinical information including patient background, sampling sites, and tissue diagnosis has been registered in the EDC system via the EMR terminal. After that, the pathology specimens were registered in the clinical specimen information management system and labels are issued. We verified that in the clinical specimen information management system, subject IDs issued by the EDC system were registered in conjunction with to clinical specimen IDs, and that it was possible to check clinical information on the EDC system using subject IDs.

3.2. Integrated management of clinical information, medical image, and clinical specimen information

We have developed a medical image collection system that automatically selects, anonymizes, and transfers medical images based on the EDC information [5]. By combining the clinical specimen information management system with our medical image collection system, the integrated management of clinical information, medical image, and clinical specimen information, automatically linked to the same subject ID in each clinical study, will become possible (Figure 3).

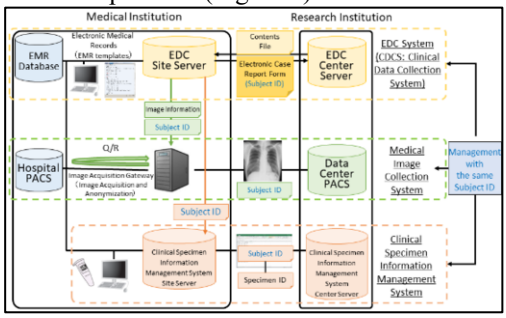

Figure 3. Integrated management of clinical information, medical image, and clinical specimen information.

4. Discussion

When an EDC system and a specimen management system exist separately, it is necessary to create a correspondence table separately to manage specimen information. By using the specimen information management system that we have developed, it is possible to efficiently link and manage clinical information and specimen information. Moreover, when combined with the image collection system, integrated management of clinical information, medical image, and clinical specimen information is possible. Therefore, this specimen information management system may be expected to provide

the platform for big data analysis utilizing clinical information, medical image, and omics data obtained from clinical specimens in multicenter clinical studies. In this study, the workflow of the system was verified at a single institution, and in the future, workflow verification at multiple institutions should be conducted, also considering compliance with IT standards for workflow management.

5. Conclusions

We have developed the clinical specimen information management system that can automatically anonymize specimen information and link it to subject ID in clinical study.

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