

“SS-MIX2 Standardized Storage”

**explanation of the structure and guidelines for
inplementation**

Ver. 1.2

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Revision History		
Date	Version	Details of revisions
2012/3	Ver.1.0 rev. 20120330	
2014/10	Ver. 1.2 *	<ol style="list-style-type: none"> 1 . In the item necessary for the folder structure "date of care,"for an order with undecided examination date for which the date of care is not determined, a description to establish the date the order is made was added. (P.8) 2 . With regard to the file unit for disease name information in the file naming conventions, we added a description to store all information on a disease name in one file instead of the expressions in one order. (P.13) 3 . As I did not associate descriptions that is dates when is "transaction time" in file name in "occurred date" required item, roller was sent and value of MS H-7 direct, such descriptions. (P.14) 4 . In the considerations for transactional storage feature, descriptions relating to management were added. (P.40) 5 . To the layout of the index database, a description not to deny the existence of other items in the minimum configuration of the table item was added, as well as further describing the examples of an additional "UniqueID" item that is to be the primary, primary key. (P.43)

*In order to unify the "SS-MIX2 Standardized Storage Specifications" and the versions, the notation of Rev was abolished and it shall be expressed in versions.

In addition, "Ver. 1.1" does not exist.

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1 Introduction

1.1 About SS-MIX

The Standardized Structured Medical record Information eXchange (SS-MIX) aims at promoting/developing the results of the standardized electronic medical chart information exchange system development commission project conducted by the Health Policy Bureau of the Ministry of Health, Labour and Welfare in FY 2006 throughout the country.

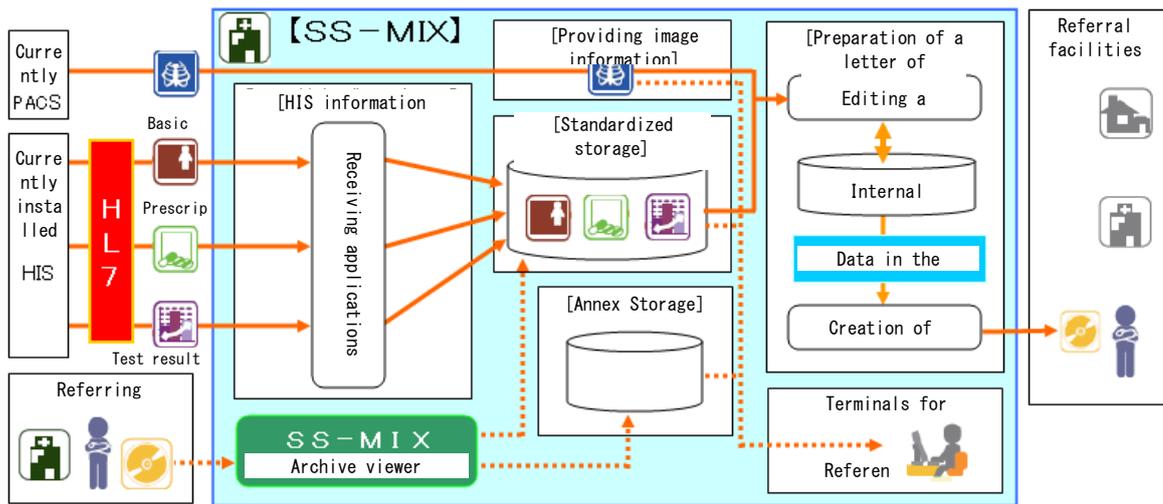


Figure 1.1-1 SS-MIX conceptual diagram1

Items stipulated in SS-MIX include as follows.

- (1) Hospital Information System (HIS) information gateway telegraphic message specification
- (2) “Standardized Storage Specification” directory structure
- (3) Electronic medical information CD and Patient Referral Document CD specification (These are registered in the HELICS code as the “patient referral document and electronic medical data document: first edition”)

1.2 Target

This document is targeted to employees of medical facilities or vendor engineers engaged in development/introduction/operation/maintenance of a hospital information system, and explains the “SS-MIX Standardized Storage” (hereinafter referred to as the “Standardized Storage”) as the “storage to store the standardized medical information” specified in the Standardized Structured Medical record Information eXchange (SS-MIX).

1.3 About expansion of the “Standardized Storage” (“Annex Storage”)

In the “Standardized Structured Medical record Information eXchange” (hereinafter referred to as SS-MIX) only medical information already specified as the standard

specification such as HL7Ver2.5, HL7 CDA R2, DICOM, etc. was to be stored in the “Standardized Storage”. However, the need for data management related to medical information for which standard specifications are not yet set is also increasing as the development of information sharing among systems within a medical facility or the medical care coordination.

Accordingly, in order to deal with non-standardized data with the same configuration as the “Standardized Storage” this document also introduces the expansion specifications of the “Standardized Storage” (hereinafter referred to as the “Annex Storage”).

1.4 Purposes

This document aims to give the following technical explanation on “Standardized Storage”

- (1) Concept and explanations of the structure
- (2) Methods of introduction/construction/operation
- (3) Matters to be considered
- (4) A guide to the preparation of an application utilizing the “Standardized Storage”
- (5) Storing data in the “Annex Storage”

1.5 Scenes where utilization of the “Standardized Storage” and “Annex Storage” is expected.

(1) Ensuring continuation of medical information

As a fate of an IT system, it is unavoidable that the hospital information system has to be replaced after certain period of time in order to deal with sophistication of user requirements, dilapidation of hardware, obsolescence of system function, etc. The vendor providing the system is often replaced at the time of the system replacement. At this occasion, how to deal with the conversion of medical information is an important issue for ensuring continuity of data and reducing the costs/number of man-hours/duration.

Continuity of data at the time of conversion can be ensured by having the “Standardized Storage” where medical information written in accordance with the standard specification is stored and the “Annex Storage” where data files that are created in the uniform format within a medical institution, but it cannot be called a standard specification, is stored and by being able to access these storages in publicly available ways.

(2) Repository in community healthcare coordination

As a measure against lack of and regional maldistribution of physicians and medical resources, concentration of patients in the regional core medical facility, etc., the need for the enhancement of community healthcare coordination has been clamored for. In recent years, cases where medical information is shared among different

medical facilities through networks are not rare.

However, the operated hospital information systems differ significantly from institution to institution, in terms of the providing vendor, version of the software, etc. The reality, therefore, is that new development/introduction activities for cooperation are conducted under the local contracts for each combination of these. Needless to say, it is essential that medical care information itself is recorded in accordance with a standard specification in order to promote reciprocal information exchange among medical facilities in such an environment. The ways to gain access to it also needs to be publicly available.

The above-mentioned problem can be solved by extracting the medical care information only about the patient eligible for the regional cooperation from the hospital information system to the “Standardized Storage” and “Annex Storage” and making it an externally open repository.

(3) Information sharing among multiple vendors

A hospital information system is composed of various division systems centering around the electronic medical chart/order entry system. These division systems include laboratory testing, dispensing of pharmaceuticals, RIS, PACS, endoscope, transfusion management, food service and so on and so forth, and each of these often needs information that is managed by the electric medical chart/order entry system, such as basic patient information/medical history/transfer history, prescription history and test results. In order to eliminate the absurdity of double input, intelligence ties with the electric medical chart/order entry system is essential, and information has conventionally been tied based on the specification specific to each division. It is “duplication of effort due to the system configuration” and nothing but a waste of people/materials/costs/time.

By utilizing the “Standardized Storage” and “Annex Storage” by placing them in the center of the intelligence ties, it is possible to eliminate this duplication of effort due to the system configuration.

(4) Utilization as backup information

Hospital information systems are exposed to risks such as large-scale disasters and in-hospital network failure, etc., but medical facilities have to continue their clinical practice even in the case when the hospital information system is disabled.

Because of the following characteristics, the “Standardized Storage” and “Annex Storage” can be utilized as the resources that provide the minimal information required for medical practice at the time of disaster/failure.

- It is designed to be utilized under the minimum, license-free IT resources.
- It is independent of technologies/products by a specific company or vendor.

- Given the recent situations surrounding storage media, medical information for as long as 5 years can be stored in a portable medium even for a large-scale medical facility.
- No special knowledge/skills in IT are needed to handle it.

2 Configurations of “Standardized Storage” and “Annex Storage” Describing configurations that are common to “Standardized Storage” and “Annex Storage”

2.1 Concept

As the storage tool for spreading and promoting exchange of the standard medical care information, the concepts of “Standardized Storage” and “Annex Storage” are as follows.

- (1) It should be used in all medical treatment facilities.

Almost all medical treatment facilities do not have full-time employees with knowledge and skill on hospital information system and there are various kinds of forms, for example, differences in the medical properties, such as general hospital/special hospital, distinction between presence or absence of hospitalization facilities, and their scale, management base. In all these medical treatment facilities in Japan, it shall be available.

- (2) The costs at the time of introduction/management should be suppressed.

The costs for software maintenance after introduction, etc. should be able to be suppressed without investments except for hardware including server and network equipments at the time of introduction.

- (3) Relying on technologies and products of specific companies and vendors should be avoided.

In addition to the viewpoint of costs of (2), from the perspective of ensuring continuity and availability of data in dealing with medical information, it should be freely licensed and be able to be introduced and managed by using only standard technologies which are widely spread.

- (4) It should have a structure that everyone can understand easily.

It should be the structure that all engineers engaging in hospital information system can understand and use easily without special education and training.

2.2 Physical structure

- (1) Storage method

- ① Under the concept as mentioned above, “Standardized Storage” and “Annex Storage” use the directory structures of hierarchized folders and files by the file management system that is generally utilized in a computer operating system to perform filing and storing of the medical care information.
- ② In hospital information systems, such as order entry and electronic medical chart, focusing on the fact that most of the services begin with identification of target patients (Patient Oriented Approach), key information in storage and search of medical information is univocally restricted to patient ID/medical treatment date and data type in unmistakable.
- ③ Storage rules are stipulated in hierarchical structure of folder.

- ④ For 2., because of functional necessity of business application utilizing “Standardized Storage”, retrieval by items and combinations except for patient ID/medical treatment date/data type may be needed. As described in 1., specific business database management system is not simulated in “Standardized Storage”, but indexing information for such a application as a function expansion can be managed as external information.

(2) Storage rules

Storage rules of folders and files in the file management system are stipulated as follows.

- ① Root folder for applicable medical treatment facility is stipulated.
The name of “root folder” is optional, but if “Standardized Storage” is applied as a measure to disaster and a foundation of community healthcare coordination, considering that “Standardized Storage”s of multiple medical facilities are needed to be stored in identical logical disk drives, medical facility ID of applicable medical institution is recommended to be configured to the folder name. In addition, this “medical facility ID” means the codes consisting of 10 digits of prefectural numbers (2 digits) + institution division codes (6 digits) + check digit (1 digit) based on “Reference material of file image of specific medical examination and specific health guidance of Ministry of Health, Labour and Welfare 5(p7,8)” and “JAHIS basic data set applicable guideline Ver2.1(p4)”.
- ② Consideration in the case that “Standardized Storage” and “Annex Storage” are divided into multiple volumes for management
 - 1) When volumes require to be divided according to the period of medical information to be stored
 - 2) When volumes require to be divided according to the data type
 - 3) When storage requires to be established in each one because the contents of ADT vary in case of responding to the systems of medical department and dentistry department
 - 4) When the storages of multiple medical facilities are managed in one place

As described above, the case of “Standardized Storage” or “Annex Storage” are divided into multivolume can be thought for the purpose of variety of use. (See 4.4 as described below) In this case, following the medical facility ID, it is overviewed that any identifier is attached and the folder name of the “root folder” is set.

- ③ In subordinate of the root folder, in order to identify the patient, “patient ID folder” that the patient ID is set to be the folder name is arranged. However, to prevent response deterioration due to storage of multiple folders (number of patients registered in such medical institution) in the root folder, patient ID is

separated by 3 digits to be hierarchized in 3 levels.

- ④ In subordinate of "patient ID folder", following 2 types of folders are arranged.
 - 1) Folder that contains patient's basic information (folder name is shown to be "-"(hyphen))
 - 2) Medical treatment date folder of the medical treatment date that falls under medical information to be stored
- ⑤ In subordinate of "Medical treatment date folder" in 4.2), "Data type folder" that falls under data type is arranged.

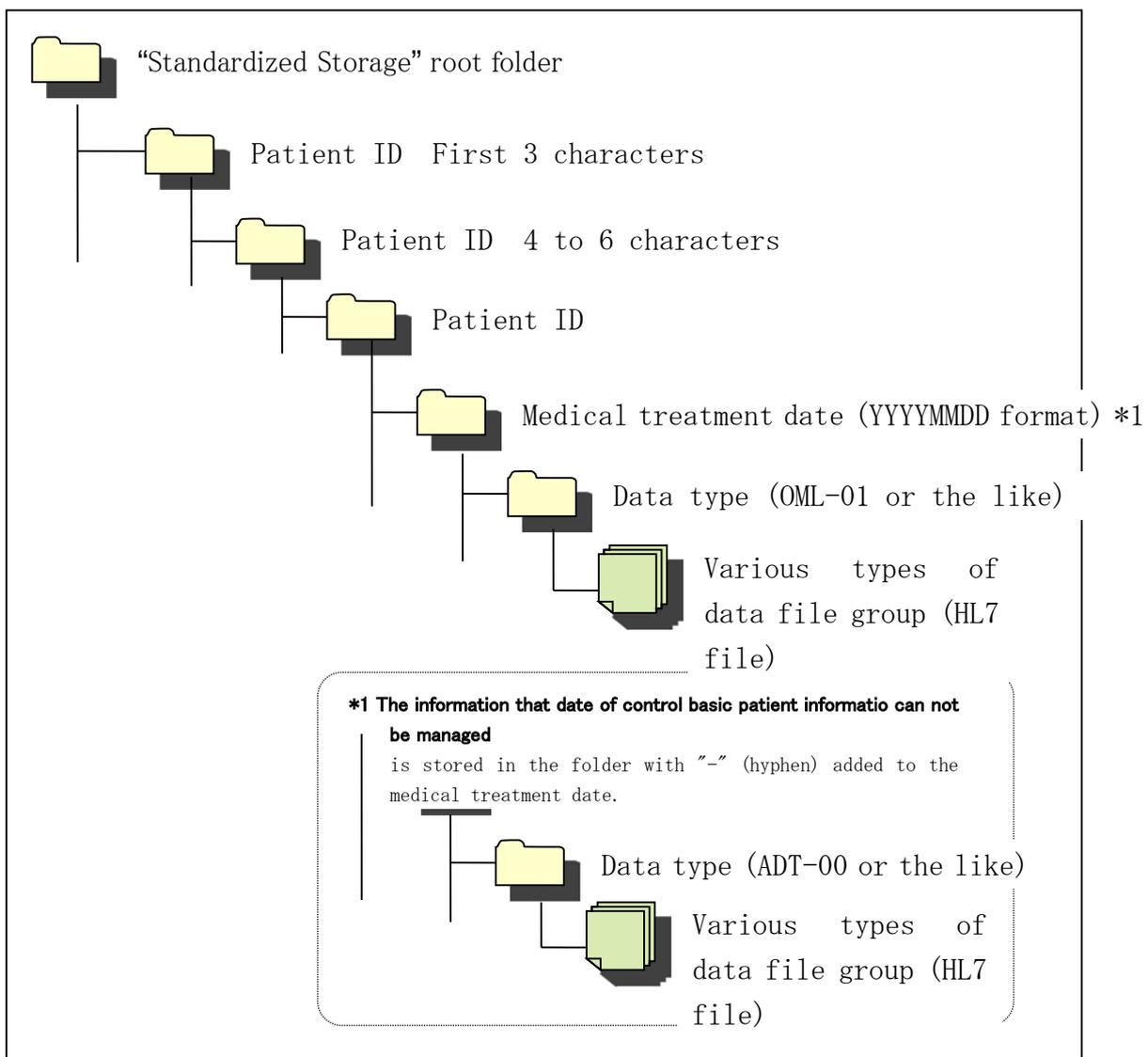


Fig. 2.2-1 Storage rules1

2.3 Items necessary for the folder configuration

As describe above, in order to name the folder configuring “Standardized Storage” and “Annex Storage”, the iformation with meaning is required. Necessary items and contents are indicated as follows.

Table 2.3-1 Items necessary for the folder configuration1

No	Item	Description
1	Patient ID	<p>ID to identify the patients uniquely in the medical facility It is set in alphanumeric 6 characters or more. * In each medical facility, ID digit number needs to be secured in 6 characters or more. ("123456" is different ID from "0123456") In the hospital information system etc, if patient ID may be expressed in 6 digits or less, characters for fill-in-the-blank are set to be 6 digits or more and such characters for fill-in-the-blank are filled with "left-justified" or "right-justified" to be characters with 6 digits or more. It should be considered as a patient ID for storage according to this. Example 1) If it does not reach 6 digits, fill "0" in left side of the value to be 6 digits (left side zero) Example 2) If it does not reach 6 digits, fill "-" in the right side of the value to be 6 digits. "Standardized Storage" is built up, or application to be seen needs to correspond the patient ID formated to 6 characters or more in accordance above rules.</p>
2	Medical treatment date	<p>The date that applicable medical information was prepared (clinical practice was performed, or considered to be performed) is expressed in-Christian Era 8 digits (YYYYMMDD). In the case of not being medical treatment, but managing events including the patient transfer, applicable date is set. Like the patient's basic/diseases/allergy, basic patient information without concept of dates uses "-" (hyphen). If the examination can not be defined clearly, for example, an order with undecided medical treatment date etc, the date of the order entery date shall be configured necessarily. - (hyphen) should not be fomulated.</p>

No	Item	Description
3	Data type	Identification characters for distinguishing data, such as prescription, clinical test etc. For prescription, see below.

- 3 Storage of medical information in “Standardized Storage”
Specifications of “Standardized Storage” only for medical information already stipulated as standard specifications including HL7Ver2.5, HL7 CDA R2, DICOM that were prescribed in SS-MIX, etc are described. In addition, this document does not mention for the contents of medical information data to be stored. For standardized content of medical information data, see “SS-MIX Standardized Storage Specification” separately.
- 3.1 Storage of medical information that is described in HL7Ver2.5
- 3.1.1 Rules of physical structure
- (1) All the items in [2.2 Physical structure] are followed to manage the patient ID and the medical treatment date.
 - (2) Data Type folder
Data type folder is provided under the “medical treatment date folder” in the hierarchical structure to distinguish the medical information in the identical medical treatment date. In the “Standardized Storage”, the “data type” is prescribed as described below to determine the type of data in the folder structure. For details, see “SS-MIX Standardized Storage Specification”.

Table 3.1-1 Data type1

No	Data type	Name	HL7 Message type	Remarks
1	ADT-00	Update of patient's basic information	ADT^A08	
2	ADT-00	Deletion of patient's basic information	ADT^A23	
3	ADT-01	Change of investigator	ADT^A54	
4	ADT-01	Cancellation of investigator	ADT^A55	
5	ADT-12	Reception of outpatient physical examination	ADT^A04	
6	ADT-21	Hospitalisation plan	ADT^A14	
7	ADT-21	Cancellation of hospitalisation plan	ADT^A27	
8	ADT-22	Conduct of hospitalization	ADT^A01	
9	ADT-22	Cancellation of conduct of hospitalization	ADT^A11	
10	ADT-31	Conduct of staying outside	ADT^A21	
11	ADT-31	Cancellation of conduct of staying outside	ADT^A52	
12	ADT-32	Conduct of return from staying outside	ADT^A22	
13	ADT-32	Cancellation of conduct of return from staying outside	ADT^A53	
14	ADT-41	Plan of change of department/building (change of room/bed)	ADT^A15	
15	ADT-41	Cancellation of plan of change of department/building (change of room/bed)	ADT^A26	
16	ADT-42	Conduct of change of department/building (change of room/bed)	ADT^A02	
17	ADT-42	Cancellation of conduct of change of department/building (change of room/bed)	ADT^A12	
18	ADT-51	Plan of discharge	ADT^A16	
19	ADT-51	Cancellations of plan of discharge	ADT^A25	
20	ADT-52	Conduct of discharge	ADT^A03	
21	ADT-52	Cancellations of conduct of discharge	ADT^A13	
22	ADT-61	Registration/update of allergy information	ADT^A60	Addition
23	PPR-01	Registration/update of disease name (history) information	PPR^ZD1	Add
24	OMD	Foods order	OMD^O03	
25	OMP-01	Prescription order	RDE^O11	Change

No	Data type	Name	HL7 Message type	Remarks
26	OMP-11	Prescription conduct notice	RAS^O17	Addition
27	OMP-02	Injection order	RDE^O11	Change
28	OMP-12	Injection conduct notice	RAS^O17	Addition
29	OML-01	Specimen examination order	OML^O33	
30	OML-11	Specimen examination result notice	OUL^R22	Addition
31	OMG-01	Radiological examination order	OMG^O19	
32	OMG-11	Notice of radiological examination conduct	OMI^Z23	Addition
33	OMG-02	Endoscopy order	OMG^O19	Addition
34	OMG-12	Notice of endoscopy conduct	OMI^Z23	Addition
35	OMG-03	Physiological examination order	OMG^O19	Addition
36	OMG-13	Notice of physiological examination result	ORU^R01	Addition

3.1.2 Naming conventions and storage forms of various data file

Under the "Data type folder" described above, the data file that various medical information described in HL7Ver2.5, etc was recorded is stored.

The file to be stored under this structure is not deleted physically (DELETE) and new file requires to be always created. It is a policy that the file before modification or deletion is left as a history under the folder. Thus, because clinical practice of type that falls under invalid file as revision history or such a folder may be performed several times (in the case of performing several cases of prescriptions or examinations on the same day), multiple files may be present under the folder. Therefore, consideration is needed to uniquely arrange these file names.

In addition, for the storage of information that data, such as the test result, etc. occur successively in time series, conventionally, rules to store file is established, assuming that "cancellation data of latest information" + "newly-generated data" are sent in a set. Therefore, "(by human) error correction" could not be distinguished from "replacement due to occurrence of recent result". Then, in this guideline, "2: past history" is newly defined in the condition flag to change the naming rule so that "as a result at one point" can be clearly distinguished from "modification". For details, see [3.1.4(2) 6. Control of sending application and processing of receiving application to sender] and [3.1.4(3) 1. Data construction flow of "Standardized Storage"].

Naming rules for uniquely arranging file name are described below.

(1) File Naming Rules

As described below, file name where items with meaning that can identify patient/data are combined with "_ (underscore)" is configured.

Patient ID_clinical treatment date_data type_order No_occurrence date_clinical treatment department_code_condition flag

In the value of each item consisting of above file name, "_ (underscore character)" should not be contained.

(2) Required item for file naming

The required items and contents to determine file name are as follows.

In addition, in "SS-MIX Standardized Storage Specification", it is assumed to define as 1 file = 1 message = 1 order. Therefore, file name is determined based on the prerequisite that no multiple orders are registered within one file.

Depending on the hospital information system, the disease name information may be represented by 1 disease name = 1 order. However, file is not created for every 1 disease name = 1 order here and all disease name informations are represented by one file. In other words, the disease name information is created by file name with the medical treatment date = "-(hyphen)" without concept of date as with allergy.

Table 3.1-2 Required item for file naming2

No	Item	Description	deal with HL7 items
1	Patient ID	Same as required items for folder structure and	PID-3
2	Medical treatment date		See Table 3.1-3
3	Data type		See Taable 3.1-1
4	Order No	<p>Identification number for identifying order (physician's direction)</p> <p>The version number/trials number of order may be included in order No by message, but the number that version number and trials number are removed by modification and deletion is set.</p> <p>For the data that is not managed by order No, such as patient's basic information/disease name/allergy information etc, ALL9 (15 digits) is set. If multiple data can exist on the same date for hospitalization/discharge, change of hospital ward, etc, the 1 days, the number that occurrences order on the same date can be identified should be configured.</p>	ORC-2

No	Item	Description	deal with HL7 items
5	Occurrence date/time	<p>Transaction date/time expressed in the format of YYYYMMDDHHMMSSFFF (millisecond)</p> <p>Applicable item aims to store the order of novel/modification/deletion, etc., of order, order of examination result in the same order No in occurrence order of time-series without duplicating the filename of the message file. Therefore, generally, the date and time that message was sent as transaction (if file is directly created, file creation date and time is applied.) is configured. For example, if past information is created historical data at a time in batch process, a file is created in ascending order of the occurrence date and time of individual message to set the creation date itself. Therefore, the transaction date and time of individual file should be different value.</p>	(Not applicable)
6	Clinical treatment department code	<p>Clinical treatment department (input organization) code</p> <p>Code of HL7 message "ORC-17" or equivalent value is configured.</p> <p>If clinical treatment department code itself is not held, default value defined within the medical facility, such as "-" or "000" in fixed value is configured.</p>	ORC-17 PV1-10
7	Condition Flag	<p>Flag to identify if the file is valid or not</p> <p>1: valid 0: invalid (deletion) 2: past history</p>	(Not applicable)

Table 3.1-3 Items by HL7 message corresponding to medical treatment date3

No	Message type	Message name	Item
1	ADT^A08	Update of patient's basic information	-
2	ADT^A23	Deletion of patient's basic information	-
3	ADT^A54	Change of investigator	-
4	ADT^A55	Cancellation of investigator	-
5	ADT^A04	Reception of outpatient physical examination	PV1-44 (date of receipt)
6	ADT^A14	Admission plan	PV2-8 (hospitalization scheduled date)
7	ADT^A27	Cancellation of hospitalization plan	PV2-8 (hospitalization scheduled date)
8	ADT^A01	Hospitalization conduct	PV1-44 (hospitalization date)
9	ADT^A11	Cancellation of hospitalization conduct	PV1-44 (hospitalization date)
10	ADT^A21	Conduct of staying outside	EVN-6 (staying outside date)
11	ADT^A52	Cancellation of staying outside conduct	EVN-6 (staying outside date)
12	ADT^A22	Conduct of return from staying outside	EVN-6 (return from staying outside date)
13	ADT^A53	Cancellation of conduct of return from staying outside	PV2-47 (return from staying outside date)
14	ADT^A15	Plan of change of department/building (change of room/bed)	PV2-8 (Date of change of department/building)
15	ADT^A26	Cancellation of plan of change of department/building (change of room/bed)	PV2-8 (Date of change of department/building)

No	Message type	Message name	Item
16	ADT^A02	Conduct of change of department/building (change of room/bed)	EVN-6 (Date of change of department/building)
17	ADT^A12	Cancellation of conduct of change of department/building (change of room/bed)	EVN-6 (Date of change of department/building)
18	ADT^A16	Discharge plan	PV2-9 (discharge scheduled date)
19	ADT^A25	Cancellations of discharge plan	PV2-9 (discharge scheduled date)
20	ADT^A03	Discharge conduct	PV1-45 (discharge date)
21	ADT^A13	Cancellations of discharge conduct	PV1-45 (discharge date)
22	ADT^A60	Registration/update of allergy information	-
23	PPR^ZD1	Registration/update of disease name (history) information	-
24	OMD^O03	Foods order	ORC-15 ORC-9 SPM-17, OBR-7 or the like
25	RDE^011	Prescription order	
26	RAS^O17	Prescription conduct notice	
27	RDE^011	Injection order	
28	RAS^O17	Injection conduct notice	
29	OML^O33	Specimen examination order	
30	OUL^R22	Specimen examination result notice	
31	OMG^O19	Radiological examination order	
32	OMI^Z23	Notice of radiological examination conduct	
33	OMG^O19	Endoscopy order	
34	OMI^Z23	Notice of endoscopy conduct	
35	OMG^O19	Physiological examination order	
36	ORU^R01	Notice of physiological examination result	

(3) Special instructions

- ① Do not append the extension to a file.

- ② In the former guideline, it was specified that "there is no definition particularly with regard to character encoding schemes of data in a file (HL7Ver2.5)", but, following "SS-MIX Standardized Storage Specification" and medical standards, and the data exchange agreement, data shall be stored in ".JIS", the character code of a message itself.
- ③ In the storage, etc of information, such as test results, whose data occur in time series successively, the history of identical clinical practice (medical care data for which patient ID/medical care date/data type/order No. are identical) is managed in chronological order.

In the conventional storage rules, as for these history files (files except for the file that falls under the latest information), it was impossible to determine whether a new history file was added to correct some error or it was replaced because any new information occurred in time series. In this guideline, to distinguish these cases expressly, the identification of "2: past history" was added to the condition flag.

To store the history management information in the same clinical practice, the procedure of "storing new data as valid(1) data after making the existing valid(1) data a past history(2)" is added to the conventional procedure of "storing new data as valid(1) data after making the existing valid(1) data invalid(2)".

However, the user side shall decide whether test results successively occurring in the course will be kept in the description of "past history" or not, and such a management is not prescribed as essential in this guideline. It is intended to show the policy of applying the idea of past history in the case where it is necessary to distinguish "error correction" and "latest data at one time point."

- ④ You shall store cancellation messages and delete order messages as files as well. In the former guideline, the measures of making the existing file invalid by nullifying the existing file without storing "cancellation message (ex. admission cancellation)" for canceling data and "delete order messages" were taken, but these messages are also deemed as storage targets.

(3) Example of laboratory test notice

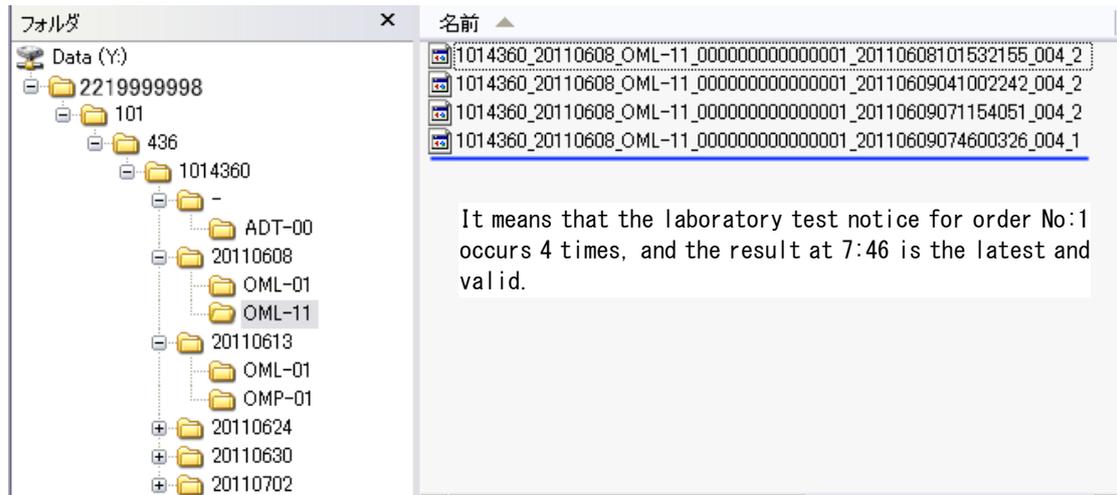


Figure 3.1-3 Example of laboratory test notice3

3.1.4 Procedures of data building

The procedures of preparing a data file to store in the “Standardized Storage” are described as follows.

(1) Means of building “Standardized Storage”

The following 2 methods to record medical information in the “Standardized Storage” are assumed in SS-MIX. Whichever method may be taken, the hospital information system side needs to implement the function to edit HL7Ver2.5 messages.

① Method to use “HIS information gateway receiving application”, the deliverable of SS-MIX

After running “HIS information gateway receiving application” provided by SS-MIX spread promotion consortium on the “Standardized Storage” side, the hospital information system side transmits the message edited with HL7Ver2.5 by TCP/IP socket in response.

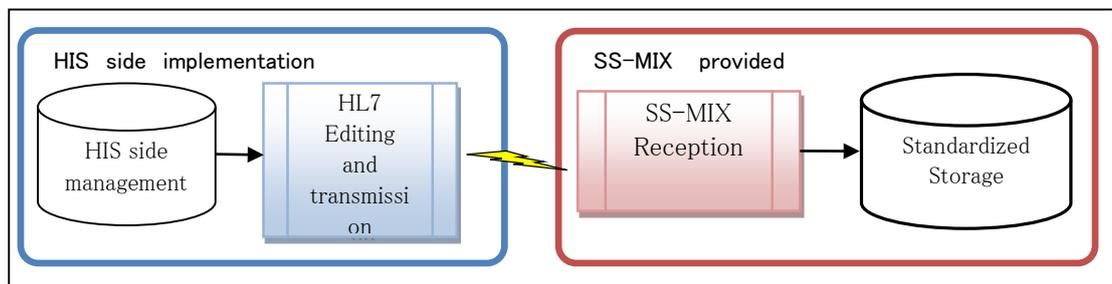


Figure 3.1-4 Use of HIS information gateway reception application⁴

② Method to directly access the “Standardized Storage”

The hospital information system side edits the medical care information files to store, and performs file accessing to the configuration based on the file folder structure of SS-MIX Standardized Storage” to build the “Standardized Storage”.

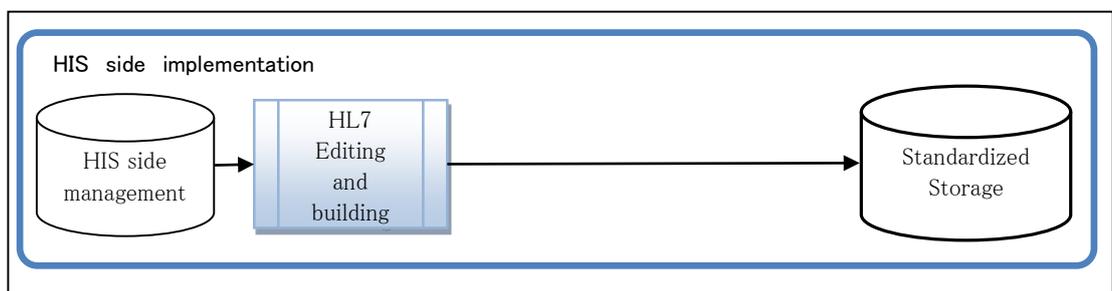


Figure 3.1-5 Direct access to the “Standardized Storage”⁵

- (2) Communication procedures of using HIS information gateway receiving application
 The communication procedures of adopting the way to use "HIS information gateway receiving application", the deliverable of SS-MIX, are described as follows.

① Principles of communication procedures

The overall COMMUNICATION METHOD is base on HL7 communication in IHE-J Connectathon. (IHE-Japan <http://www.ihe-j.org/>)

However, in the former Guideline, the information to build the "Standardized Storage" as "ZGW" segment was contained in HL7 message, but, in SS-MIX2, it is prescribed as SS-MIX header message separately outside of HL7 message.

Accordingly, a message handles the exchange of "SS-MIX header message" + "HL7 message" as one set.

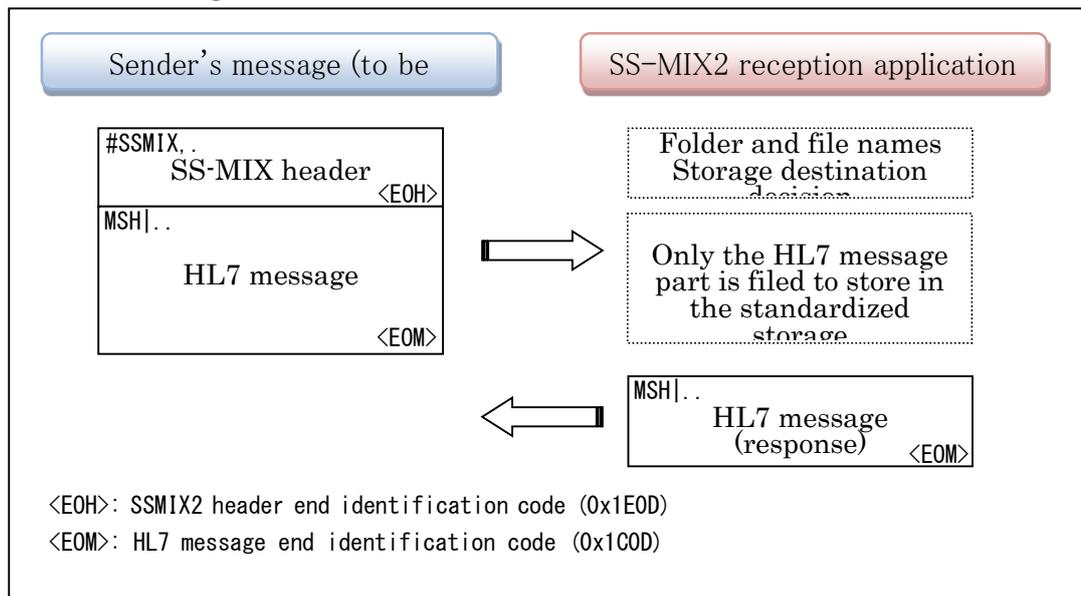


Figure 3.1-6 Communication message6

Refer to the [Definition of 4. SS-MIX Header] described below for the SS-MIX header.

② Socket communication procedural diagram

The example of processing flow on the sender's application is as follows.

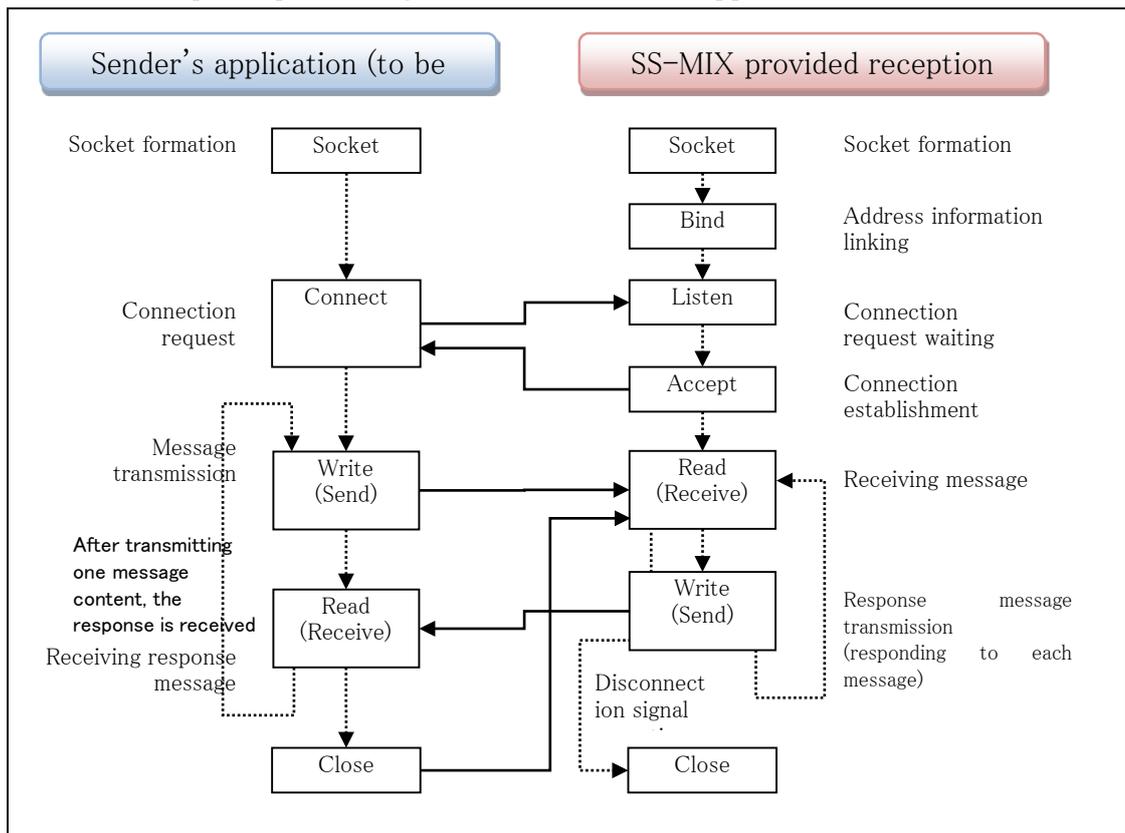


Figure 3.1-7 Socket communication procedure7

③ Special notes on communication procedure

- 1) It is socket Communication by TCP/I P.
- 2) The former Guidelines established that the port on the receiver application should always be one, but these guidelines shall abolish this restriction. That is to say, the receiver application can receive multiple messages by one port or it can receive separately designated messages by multiple ports. The medical facility shall specify the number of ports they use and establish port numbers. The sender application shall send messages to the designated port.
- 3) At the point when the application sending the data establishes the connection and the sent message is cut (finished sending the message) the sender cuts (releases) the connection.
- 4) The receiver can only listen to the establishment of connection and it does not connect/cut the connection. (The receiver may cut the connection due to termination of application/failure of communication line, etc.)
- 5) Every time a message is sent, a response message will be returned. (To the ADT message the ACK message is returned. Different response messages are sent to different sent messages, so see the

“SS-MIX Standardized Storage Specifications” and the protocols of JAHIS/HL7 for details.)

To errors such as failure to identify the telegraph received by the receiver as an HL7 message, no HL7 response message corresponding to the sent message shall be returned. In such a case, it shall be replied by a message specified in [5.5 Response error message for failure to identify as an HL7 message] (to be described).

- 6) According to the “SS-MIX Standardized Storage Specifications” before sending a message as MLLP (Minimum Lower Layer Protocol), it is designed to send the “begin block <VT> (0x0b),” but MLLP is not adopted in IHE-J, so the begin block does not need to be sent.
- 7) Character code of the message (character set) is supposed to be specified by the MSH segment. With JAHIS and IHE-J, the de-dacto standard is that “ISO IR-6 (ASCII) for 1-byte characters and ISO IR87 (JIS kanji code) for 2-byte character,” so these specifications also follow this standard. In particular, note that half-size Kana characters are not accepted as standard.
- 8) The restriction in the “SS-MIX Standardized Storage Specifications” makes up one order by one message for the order system messages.
In the former guidelines, “1 MSH 1 order (OCR) is the specification for the message itself, so there is no problem in sending an n MSH portion in one connection or one Send”. However, because the SS-MIX header is added in the SS-MIX2, the communication procedure, in which every message sent receives a response message, shall be used and sending multiple HL7 messages in one send shall not be accepted.
- 9) The identifier for the end of an HL7 message is <EOM> “0x1C0D,” in the same way as before, but in these guidelines it is necessary to distinguish the SS-MIX header and HL7 message text strictly, so identifiers for the SSMIX header and the HL7 message must be given.

④ Definition of SS-MIX headers

Makes a received HL7 message into a file and names the file, as well as defining the compilation of information for storing in the physical folder in the “Standardized Storage” as an SS-MIX header.

In the former Guidelines, this information was contained in the HL7 message as a “ZGW” segment, but in the SS-MIX2, it will be distinguished from HL7 messages and treated as an SS-mix header.

Because it is information consisting of the items necessary for the folder structure and file naming, see the above-mentioned physical structures for details of each item.

An SS-MIX header shall be a message consisting of the items shown in the table

below divided by commas.

The end identifier of an SS-MIX header <EOH> shall be "0x1E0D."

*0x1E means "Record Separator" on the ASCII codes.

Table 3.1-4 SS-MIX header configuration items-4

No	Item	Description
1	SS-MIX identification	Fixed value "#SSMIX" is set.
2	Version	Indicates the version of the SS-MIX. In these specifications, a fixed value "2.00" is set.
3	Medical facility ID	An ID (10 digits) that uniquely identifies a medical facility *Based on the "Reference material of file image of specific medical examination and specific health guidance of Ministry of Health, Labour and Welfare 5 (p 7,8)" and "JAHIS basic data set application guidelines Ver 2.1 (p 4)" The code consisting of 10 digits of prefectural numbers (2 digits) + institution division codes (6 digits) + check digit (1 digit) shall be used.
4	Patient ID	ID to uniquely identify a patient within a medical facility.
5	Date of medical care	Date of medical care expressed in the 8 digits of the western calendar year (YYYYMMDD)
6	Data type	Identification characters to distinguish data such as prescription, laboratory tests, etc.
7	Order No	An identification number to specify an order (instructions from the physician)
8	Processing classification	Characters that distinguish whether the data is new or to be deleted. INS: insert "DEL": delete When the HL7 message sends a cancellation message or deletion order message, select "DEL."
9	Clinical department code	Clinical department (input organization) code
10	Transaction date/time	Date/time the message occurred expressed in date/ time (YYYYMMDDHHMMSSFFF milliseconds)

Example)

```
#SSMIX, 2. 00, 2219999998, 1014360, 20120120, OMP-01, 0000000000000001, INS, 01, 201201200945301
23<EOH>
```

- ⑤ Responses error message for the occasion where the message could not be identified as an HL7 message.

In HL7, the types of response messages for sent messages are predetermined, but when a received message cannot be correctly identified as an HL7 message, the trigger event or message control ID, etc. cannot be set. Therefore, in the conventional HL7 communication, errors were recognized by detecting transmission failure due to timeout on the sender or by receiving the HL7 response message uniquely defined after discussion between both parties.

Accordingly, in these guidelines, the HL7 response message is defined as shown below, and it shall be returned at the point when the receiver could recognize the transmission as an error.

The same response message shall also be used when an SS-MIX header cannot be identified correctly.

Table 3.1-5 List of general response messages5

ACK^ZSN^ACK	General Acknowledgment
MSH	Message header
MSA	Message acknowledgment
{{ERR}}	Error

Table 3.1-6 segment field settings6

Field	Field name/description	Settings
MSH-5	Receiving application	(null value) fixed (Originally those that MSH-3 of the sent message is transcribed)
MSH-6	Receiving medical facilities	(null value) fixed (Originally those that MSH-4 of the sent message is transcribed)
MSH-7	Date/time of message	Date/time the response transmission (receiver) application creates the message. Time zone is not specified at maximum 1/10000 second.
MSH-9	Type of message	ACK^ZSN^ACK fixed
MSH-10	Message control ID	The number with which the

Field	Field name/description	Settings
		response transmission (receiver) application uniquely identifies the response message.
MSH-11	Transaction ID	P fixed
MSA-1	Acknowledgement code	AE error fixed
MSA-2	Message control ID	[9999999999999999] fixed (Originally those that MSH-10 of the sent message is transcribed)
MSA-3	Text message	Error message *Characters within 80 bytes

The fields not shown in the table above shall be edited in accordance with the "SS-MIX2 Standardized Storage Specifications".

Example)

```
MSH|^~\&|SSMIX2|GW|||20120301093025000|ACK^ZSN^ACK|1234567890|P|2.5|||||~ISO
IR87||ISO 2022-1994<CR>
MSA|AE|9999999999999999|SS-MIX header cannot be determined.
<EOM>
```

⑥ Sender application control and the corresponding processing by the receiver application

When using the HIS information gateway receiver application, the sender application can perform the following three patterns of control by the process category of the SS-MIX header message.

1) To send a new message

With the sending application, set the required items for the SS-MIX header message and INS for the processing classification, and edit the HL7 message of clinical practices that should be additionally recorded. Then, in accordance to the above mentioned regulations, send one set of SS-MIX header and HL7 message.

With the receiving application, search the applicable storage folder in the standarzing storage for a valid data file (condition flag = 1) that matches the patient ID, date of treatment, data type, and order number of the message. If it exists, rename the history file to make it "condition flag = 2."By doing so, "2: past history," mentioned in [3.1.2(3(3.) is created.

The receiving application writes the message information as "condition flag = 1,"

2) To cancel the registered information.

With the sending application, set the required items for the SS-MIX header message and DEL for the processing classification, and edit the HL7 message of clinical practices that should be cancelled. Then, in accordance with the above mentioned regulations, send one set of SS-MIX header and HL7 message.

With the receiving application, search the applicable storage folder in the standarzing storage for a valid data file (condition flag = 1) that matches the patient ID, date of treatment, data type, and order number of the message. If it exists, rename the history file to make it "condition flag = 0" and write the cancelled message transmitted by the message as "condition flag = 0."

3) To null the corrent latest information and send a new message.

With the sending application, carry out the processes mentioned above in the order of 2) -> 1).

(3) Procedure to develop the “Standardized Storage” by direct access.

To develop the standardizing storage, follow the process mentioned in (2) until the point to edit HL7 Ver. 2.5, and then save the edited HL7 Ver. 2.5 message as a file and store it in the specified folder configuration.

As the standardizing storage configuration is as above, the simple flow and precautions are noted here.

① Flow of data building for the “Standardized Storage”

- 1) Edit HL7Ver 2.5 message stored in data managed under the hospital information system. Refer to “SS-MIX Standardized Storage Specifications” for editing contents.
- 2) Based on the patient ID, date of treatment, data type, order number, date of transaction, and treatment department code of the message data, decide the file name.
- 3) Based on the patient ID, date of treatment, and data type of the message data, decide the storage place (folder) for the “Standardized Storage”, If such folder does not exist, creat it.

- 4) If the message data is a deleted data, search the applicable storage folder of the “Standardized Storage” for a valid data file (conditions flag = 1) that matches the patient ID, date of treatment, data type, and order number. If it exists, rename the history file to make it “condition flag = 0”.

If the message data is a valid data (not deleted), search the applicable storage folder of the “Standardized Storage” for a valid data file (conditions flag = 1) that matches the patient ID, date of treatment, data type, and order number. If it exists, rename the history file to make it “condition flag = 2”. This should be done to distinguish data before replacement from the current valid data which share the same order. By doing so, “2: past history,” mentioned in [3.1.2(3) 3.] is created.

To modify the order, perform the two processes of “delete” and “new” file sequentially. With cases that the latest information will be available in phases and successively, such as test results, the valid data should be processed only as “new” in order to manage the past latest files as “2. past history” each time the new latest data became available.

- 5) Create a file in the applicable folder with the name decided at 2).
SS-MIX supposed not to create a file if it was a deleted data. However, SS-MIX2 requires file creation with deleted data as a deleted message.

② Precautions at storing data

- 1) Files to be stored should have an unique name in the storage folder. For that reason, set the date of transaction as a part of the file name.
- 2) The patient ID + date of treatment + data type + order number represents the minimal unit instructed by doctors (and clinical information is occured).

As modifications and deletion are performed in a unit, order numbers should be numbered in a way that the previous data can be identified.

3.1.5 Considerations in data migration and operation during the transitional period for those with the old version “SS-MIX Standardized Storage”

When introducing the current version to a system with a “Standardized Storage” developed with the old version, consider the followings.

In this guidelines, the old version means the first edition 1.0 and the current version 2.0.

(1) “Standardized Storage” of the old version

This guidelines recommend to handle HL7 messages of the new and old versions as a series of messages and build them as a mixed storage when intruding the current version “Standardized Storage”. Thus, when the old version “Standardized Storage” exists, we do not recommend converting it to the current version. However, there would be some points to consider and cases hard to settle in connection with collaboration with data source systems, such as the hospital information system, separating the new and old storages remains an option.

(2) Modification and cancel of messages during the transitional period from the old to new version

HIS information gateway application can cancel even the old version messages in accordance with [3.1.4(2) 6. sending application control and corresponding processes by the receiving application] when the messages stored with the old version are canceled or modified by current version messages created after switching from the old to new version.

However, modification and cancel of order/implementation messages of which data type are different between the new and old version, for example, cancelling the old version text result part of which is completed (OML[^]O33 message) with the new version text result (OUL[^]R22 message), etc. Therefore, when both exist, duplicates need to be eliminated with the refer application.

(3) Difference from the old versions and matters to be considered

① About patient’s basic/disease name/allergy information

Information about disease name and allergy was included in the patient’s basic information in the old versions (ADT[^]A08), but in the current version, they are stored in the directory different from the patient’s basic information, separated into the disease name (PPR[^]ZD1) and allergy (ADT[^]A60) message, respectively, Therefore, if disease name or allergy information occurs in the current version, the information may overlap with the disease name/allergy information stored as the patient’s basic information in the old version. Accordingly, when a disease name (PPR[^]ZD1) or allergy (ADT[^]A60) exist in the reference application, this information shall prevail and the same information in the patient’s basic

information (ADT^A08) needs to be ignored.

It also means that when only the patient's basic information is changed in the current version, the disease name and allergy information stored in the old version will be lost. In order deal with such a case, when sending the patient's basic information from the hospital information system, you also need to take measures such as sending disease name/allergy information.

- ② About prescription/injection order and information on their implementation
Volume labels are strings that uniquely distinguish the root directory of "Standardized Storage", and do not keep information on the root directory and others that depend on the physical structure, such as the server.

For prescription, only the instruction information was stored in the OMP^O09 message with the old version, but it was decided that the instruction information shall be stored in the RDE^O11 message and the implementation information in the RAS^O17 message in the current version.

Accordingly, for both prescription and injection, you need to analyze the instruction information in the OMP^O09 and RDE^O11 messages stored in the old and new directories.

- ③ About information on specimen test order and test results

In the old versions, the instruction and test result information was stored in the OML^O33 message, but the current version stores the instruction information in the OML^O33 message and the test result information in the OUL^R22 message. For this reason, in a transitional stage in the switch from the old to new version, the test result information (partially complete) may be stored in the old version and the test results obtained after the switch may be stored separately in the current version.

Therefore, when there is an OUL^R22 message as the test results for the applicable order No. when obtaining test results, the reference application needs to prioritize this and ignore the test results in the OML^O33 message so that the test results are not obtained redundantly.

3.2 Storing information relating to exchange of medical information

3.2.1 What is information relating to exchange of medical information?

In the “Standardized Storage” the following information relating to exchange of medical information is managed as well as the information described in [3.1 storing medical information described in HL7 Ver. 2.5].

(1) Data on the provision of medical information

It provides the medical information managed at the given medical facility to outside parties through external storage media such as CDs or networks, and it is classified into the following two types based on the receiver of the information and difference in nature. In the “referral letter issuance system” provided by SS-MIX, medical information is provided using CDs in accordance with the rules stipulated there.

① “Patient Referral Document” for physicians in other medical facilities.

So-called “referral letter”

② “Electronic medical information” for patients

(2) Data on the provision of medical information created at other medical facilities

Taking in and filing the data on the provision of medical information created at other medical facilities in accordance with (1) for the purpose of viewing within the given medical facility. It is also classified into two types just like (1). In the “archive viewer” provided in SS-MIX, in accordance with the rules provided there, the CD of the medical information data created and brought in by other medical facilities is taken in, and function for reference within the medical facility is provided.

(3) Image information created by other medical facilities and in compliance with the IHE-J PDI profile

Takes in and file the image created by other medical facilities and in compliance with the IHE-J PDI profile for the purpose of viewing within the medical facility. In the “archive viewer” provided in SS-MIX, in accordance with the rules provided there, the PDI CD created and brought in by other medical facilities is taken in, and function for reference within the medical facility is provided.

*PDI is an integration profile designed by the Integrating the Healthcare Enterprise Japan (<http://www.ihe-j.org>) for storing DICOM in a portable medium. See the technical framework of the Enterprise for details.

*The Patient Referral Document CD refers to a CD in compliance with the “HL7J-CDA-004_Portable Media for Clinical Document Specification” designed by IHE-J by following the PDI profile.

3.2.2 Rules for physical structure

- (1) Manages patient ID/date of care by following all the items in [2.2 physical structure].
- (2) About folders by data type

Composed in the same hierarchical structure as [3.1 storing medical information described in HL7 Ver2.5]. "Folders by data type" are set under the "date of care folder" in the hierarchical structure in accordance with the following rules.

Table 3.2-1 Data type1

No	Data type	Description
1	REF-01	"Letter of referral" created by the medical facility
2	INF-01	"Electronic medical information" created by the medical facility
3	REF-02	Contents of the "referral" CD sent by other medical facility.
4	INF-02	Contents of the "electronic medical care" CD sent by other medical facility.
5	PDI-01	Contents of the PDI CD sent by other medical facility.

3.2.3 Forms of storage of data files and naming conventions

- (1) The only difference between the medical information described in HL7 Ver. 2.5 and the Patient Referral Document created by the medical facility is that the contents of the file are the XML file. Therefore, the naming conventions shall be the same as HL7 Ver. 2.5 in [3.1.2 storage forms of various data files and file naming conventions].
- (2) A CD sent by other medical facility, including referral, contains multiple files. You are not allowed to change the contents or file names. For this reason,
 - ① Create subfolders under the "folders by type of data."
 - ② By using some kind of sequence or processing date/time managed by the system, give the folder from 1 a unique name.
 - ③ Regard the folder created at 1 as a route of the CD medium, and store the folder structure in the CD in the same form.

3.3 Transaction storage

3.3.1 What is transaction storage?

The “Standardized Storage” adopts a physical structure specializing in searching particular patient’s medical information after specifying the patient (patient ID). However,

- ① In cases where the “Standardized Storage” needs to be re-created for some reason
- ② In cases where a copy of the “Standardized Storage” is created outside the medical facilities such as a data center as measures in the event of disasters or as a base of the community healthcare coordination, using an external connection line.
- ③ In cases where it may be possible to reuse the data transmitted from the hospital information system set by these guidelines in the system other than the “Standardized Storage”.

In these cases, it is necessary to refer to medical information by focusing on the date/time the medical information was recorded in the “Standardized Storage” as a transaction (hereinafter referred to as “date and time of occurrence of transaction”).

Therefore, here, given the convenience of reusing the standardized medical information itself transmitted from the hospital information system as a data source, the transaction storage is defined as a storage specializing in referring to medical information based on the date and time of occurrence of transaction.

In this guideline, it is not mandatory to provide a transaction storage to the “Standardized Storage”, but the structure and the rules in the case of constructing the transaction storage are defined on request from the application.

3.3.2 Structure of transaction storage

(1) Storage method

- ① The transaction storage uses the directory structure of the folder and file hierarchied by the file management system that is generally employed in the computer operating system to file and store the standardized medical information that is sent from the hospital information system.
- ② As a key information, focusing on occurrence date of the transaction of the standardized medical information that is sent from the hospital information system, it is limited
- ③ The storage rules are stipulated in the hierarchical structure of the folder.

(2) Storage rules

The storage rules of folders and files in the file management system are stipulated as follows.

- ① The "root folder" for the applicable medical facility is stipulated.
- ② Under the root folder, in order to identify the calendar year of the transaction occurrence date, the "transaction occurrence year folder" is placed.
- ③ 2. Under the "transaction occurrence year folder", the applicable transaction data file is stored.

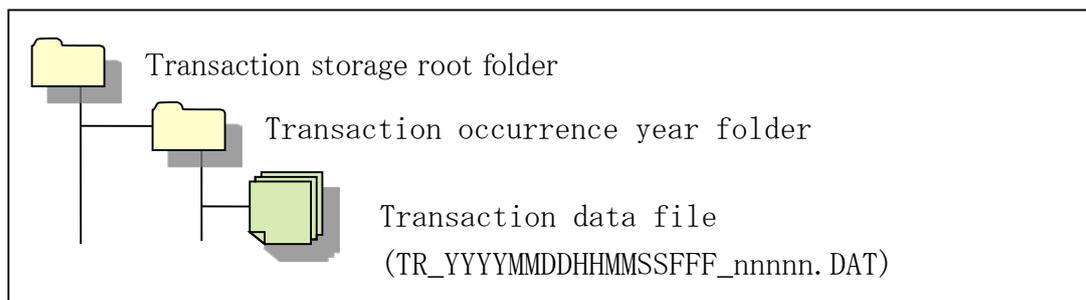


Fig. 3.3-1 Storage rules-1

(3) Transaction data file

- ① Contents of transaction data file
"SS-MIX headers" + "HL7 message" shall be successively accumulated. For details, see "3.1.4 Procedure of data construction".

- ② File naming convention for transaction data file

The file name is configured as follows.

A timestamp is a time on OS that the hospital information system starts the process to record the medical information on the "Standardized Storage", and the format is YYYYMMDDHHMMSSFFF.

In addition, considering the case that there are several processes (application) of executing writing to one "Standardized Storage", in order to identify these uniquely, a process line number is provided. For example, if "HIS information gateway receiving application" is employed, the port number that is utilized in applicable process is configured.

TR_time stamp of transaction occurrence date_process line number.DAT

Example) TR_20120331224610111_5678.DAT

It shows the transaction storage created by the process that starts recording to "Standardized Storage" at 22:46.10,111, March 31, 2012 in the process of port number 5678.

(4) Considerations in creating transaction data file

- ① Method to use "HIS information gateway receiving application" which is a deliverable of SS-MIX

By the timestamp at the time of establishing the connection of socket communication and the port number that is set in the applicable receiving application, the transaction data file is determined to create new file and write medical information that is received during the applicable socket session by additional writing. At the time of the applicable receiving application ending or the connection of socket communication being disconnected, the transaction data file that has been recorded until then is closed.

- ② Method to access the "Standardized Storage" directly

Also in this method, it is assumed to write the medical information that was occurred in some time interval in series of processing into the "Standardized Storage" from the hospital information system . Therefore, as with 1., the file name is determined by the timestamp at the time of the applicable processing application starting operation to create new file and write the medical information occurring during the applicable processing application being operated by additional writing. At the time of the applicable processing application ending, the transaction data file that has been recorded until then is closed.

In addition, for the port number, such any number that the processing system is defined uniquely is configured.

- ③ Switch of transaction data file

In both 1. and 2. mentioned above, at the time of the date of the current being changed or at the time of the file size of transaction data file under being recorded exceeding a certain amount, new file is created to switch the recording destination.

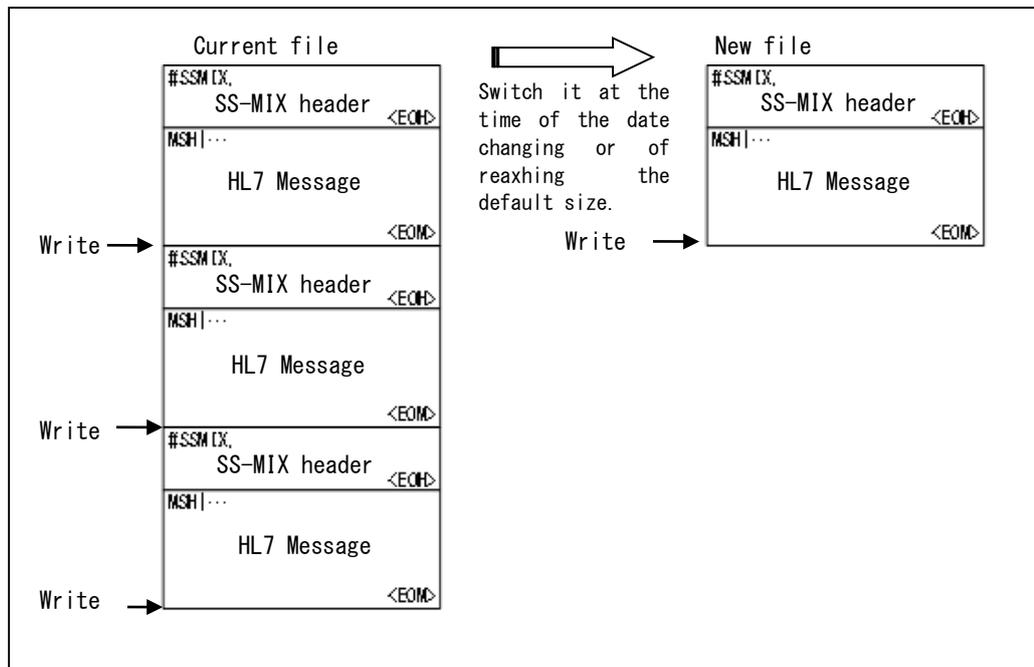


Fig. 3.3-2 Switch of transaction data file2

④ Saving and management of transaction data file

Creating the data file group held in the transaction storage is to hold the contents of “Standardized Storage” redundantly, resulting in the factor of compressing the storage capacity. Therefore, if the purpose and usage described in “3.3.1 What is a transaction storage” is met, all data within the transaction storage do not need to be retained in the same server (physical storage) permanently and the operation shall be ensured that the data are backed up in other media in a timely manner and are restored if needed. For this operation method, the storage and management policies are defined at the medical facility that introduce it.

3.4 Index database of physical storage information

3.4.1 What is an index database?

After “Standardized Storage” identifies patients (patients ID), physical structure that specialized in finding practice information of this patients is embraced. Therefore, for example, when reference is done across multiple patients, such as medical information applicable to specific medical treatment date, medical information applicable to specific clinical practice, etc, or when referring to a large amount of medical information, a great deal of burden will be applied to the system.

In order to reduce such a burden and for the application that uses the “Standardized Storage” being able to implement the search function described above easily, the relational database systems, etc are utilized to define the index database to retain the value constructing the physical structure in the database.

In this guideline, it is not mandatory to provide the database as mentioned above in the “Standardized Storage”, but it defines the structure of the table and the schema in the case of constructing the database in response to a request from the application.

3.4.2 Layout of index database (table)

Table 3.4-1 Layout of index database1

Table name: SSMIXIDX

No	Item (field name)	Type (ODBC data type)	Length	Remarks
1	Volume label (VolumeLabel)	Half-width alphanumeric variable characters (SQL_VARCHAR)	20	Identifier supporting root directory of “Standardized Storage”
2	Medical facility ID (FacilityID)	Half-width alphanumeric fixed characters (SQL_CHAR)	10	Each item value or a base value that is physical storage destination of “Standardized Storage”
3	Patient ID (PatientID)	Half-width alphanumeric variable characters (SQL_VARCHAR)	15	
4	Medical treatment date (OrderDate)	Half-width variable characters (SQL_VARCHAR)	8	

No	Item (field name)	Type (ODBC data type)	Length	Remarks
5	Data type (DataKind)	Half-width alphanumeric variable characters (SQL_VARCHAR)	16	
6	Order No (OrderNo)	Half-width variable characters (SQL_VARCHAR)	22	
7	Processing classification (ProcessingType)	Half-width alphanumeric variable characters (SQL_VARCHAR)	3	
8	Clinical department code (EnterOrgCD)	Half-width alphanumeric variable characters (SQL_VARCHAR)	5	
9	Transaction date and time (TransactionDatetime)	Half-width variable characters (SQL_VARCHAR)	17	
10	File destination directory (OutRelDirectory)	Half-width alphanumeric variable characters (SQL_VARCHAR)	180	Relative path from "Standardized Storage" root strung to volume label
11	File name (FileName)	Half-width alphanumeric variable characters (SQL_VARCHAR)	80	
12	Date and time of update (UupdateDatetime)	Time stamp (SQL_TIMESTAMP)		Date when applicable record is registered and updated

3.4.3 Positioning of Volume Labels

Volume labels are strings that uniquely distinguish the root directory of "Standardized Storage", and do not keep information on the root directory and others that depend on the physical structure, such as the server.

This is to avoid influencing the index database when the system configuration is changed by server relocation or environment changes, etc.

Therefore, the application that refers to this database to access the "Standardized Storage" needs a mechanism to understand the root directory of "Standardized Storage" that corresponds to the volume label.

Taking the use of index database into consideration, we recommend that the table should be consolidated into a single table even when multiple “Standardized Storage”s exist (2.2(2)2. Consideration to manage the “Standardized Storage” and the “Annex Storage” by splitting them in multiple volumes).

3.4.4 Expansion of index table items

The index table set out the above table defines the minimum items that can be the index of the “Standardized Storage”. The exact layout is not necessarily required and new items can be added as necessary unless the table name and the minimum items described in the above table are defined. For this reason, SQL statements to access the table cannot be implemented with functions that depend on the number of items or their order, for example omitting the name of items to be inserted from INSERT statements, using the position of items in sorting SELECT statements (ORDER BY 1,2,3, etc.), etc.

For example, as any ID that uniquely identifies records does not exist in the above definition, it would be an idea to additionally define an ID item as the primary key. This unique ID is expected to be used as “DocumentEntry.UniqueID” in the regional alliance based on IHE-ITI(XDS.b).

13	Unique ID (UniqueID)	Ennage variable characters (SQL_VARCHAR)	16	ID that uniquely identifies this record
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4 Storage of medical information in the “Annex Storage”

4.1 Necessity of the “Standardized Storage” expansion concept (the “Annex Storage”)

- Examination and interpretation reports on radiation and endoscope etc. and accompanying image information
- Standard specifications for various summaries
- Information on critical paths and regional alliance paths
- Record documents on surgery and nursing

among others, have not been established yet, but how to manage data files created in medical facilities in standard formats is an important issue.

For this reason, this section presents and calls as “Annex Storage”’s expanded specifications for storing non-standardized data in the following formats with configurations similar to the “Standardized Storage”.

- Files written in HTML, XML, etc.;
- PDF and other print image files;
- Text information and document files that were created by widely-used word-processing or spreadsheets software, and
- Image files such as JPEG, TIFF, Bitmap.

However, these applications are defined based on the agreement among users.

4.2 Rules on the physicals structure

(1) Isolation of “Standardized Storage” and “Annex Storage”

As the “Annex Storage” is configured based on the local rules set by the medical facility or software products/vendors that made the storage, it should be managed in physically, clearly separate way from the “Standardized Storage”.

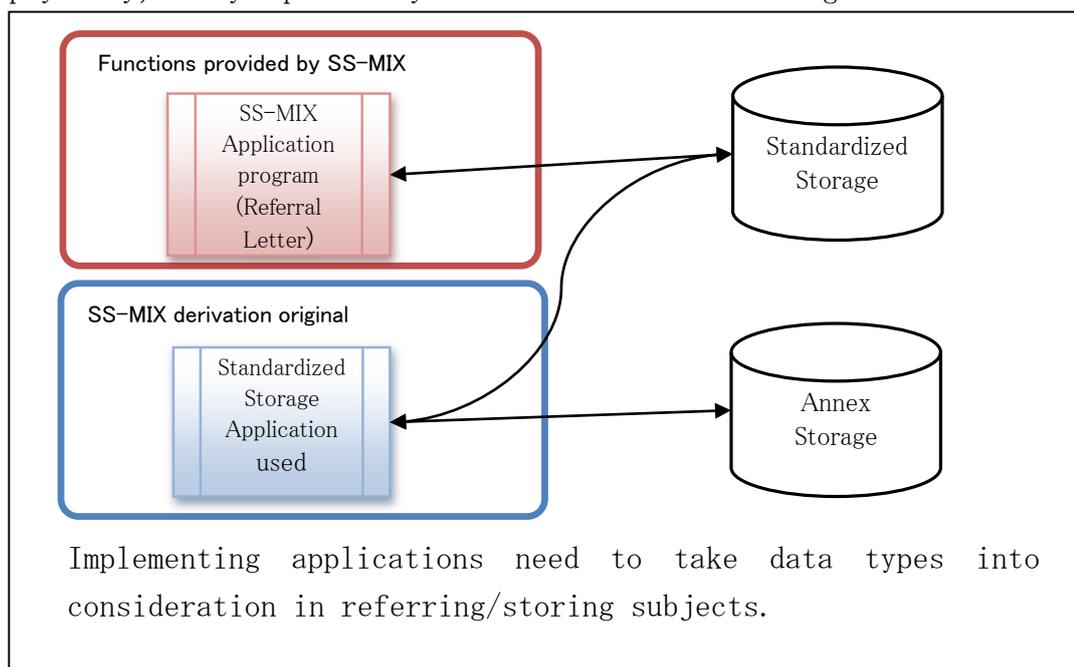


Figure 4.2-1 Isolation of “Standardized Storage” and “Annex Storage”1

For this reason, we established the following rules.

① Physical isolation of the root folder

When the root folder is defined at the top of the hierarchical structure as in 1. of [2.2(2) storage rules] but both of the “Standardized Storage” and the “Annex Storage” are being built in the same storage by the medical facility, they should not be mixed in single root folder. In other words, a separate folder should be allocated to each of the “Standardized Storage” and the “Annex Storage”.

However, we do not obligate isolation of hardware.

② Non-standardized data should not be stored in the “Standardized Storage”.

(2) Under the prerequisite of (1), follow the all items of [2.2 Physical structure] and manage patient IDs and date of treatment.

(3) Data type folders

Follow the folder configuration for patient IDs and date of treatment, and then for the folders lower than them set voluntary rules and manage these folders. We recommend setting a rule on the concept for data type folders.

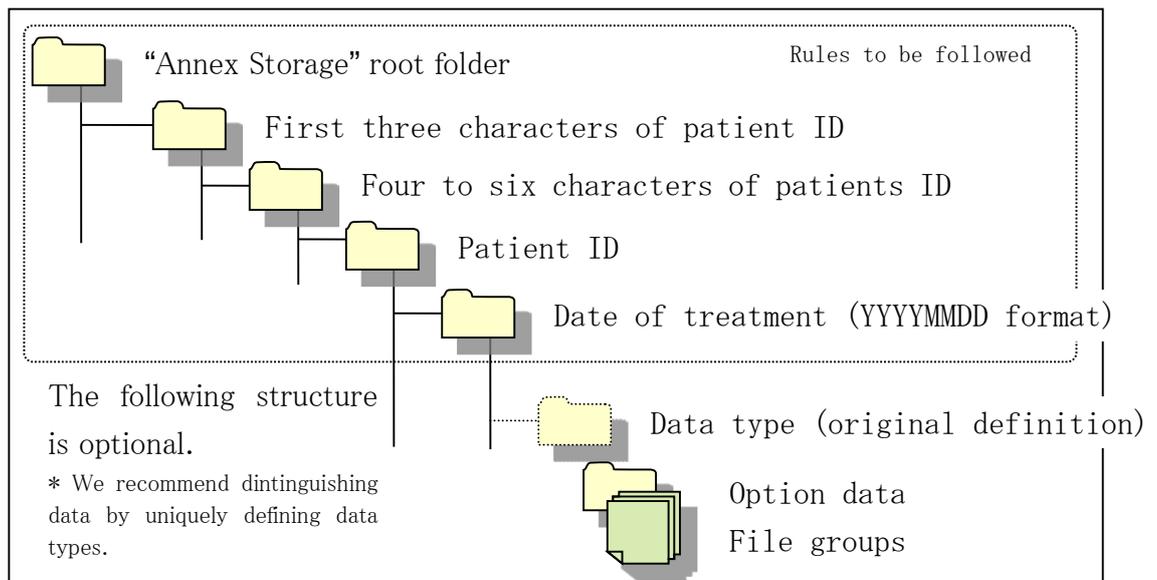


Figure 4.2-2 Storage rules2

4.3 Storage forms and naming rules for various data files

For naming data files to be actually stored, set voluntary rules and manage them based on the rules. In doing so, the following points should be considered.

- (1) We recommend selecting a name that clearly tell patient ID, date of treatment, and data type contained in the data file.
- (2) Each file in the storing folder should have a unique name. Especially when letting users decide file names, considerations are needed such as to raise their carefulness

not to select a name that is used for other file stored in the same folder or to systematically prevent using a same name.

4.4 Example of application of “Annex Storage”

The following is the way of managing the “Annex Storage” implemented by certain SS-MIX derivation application.

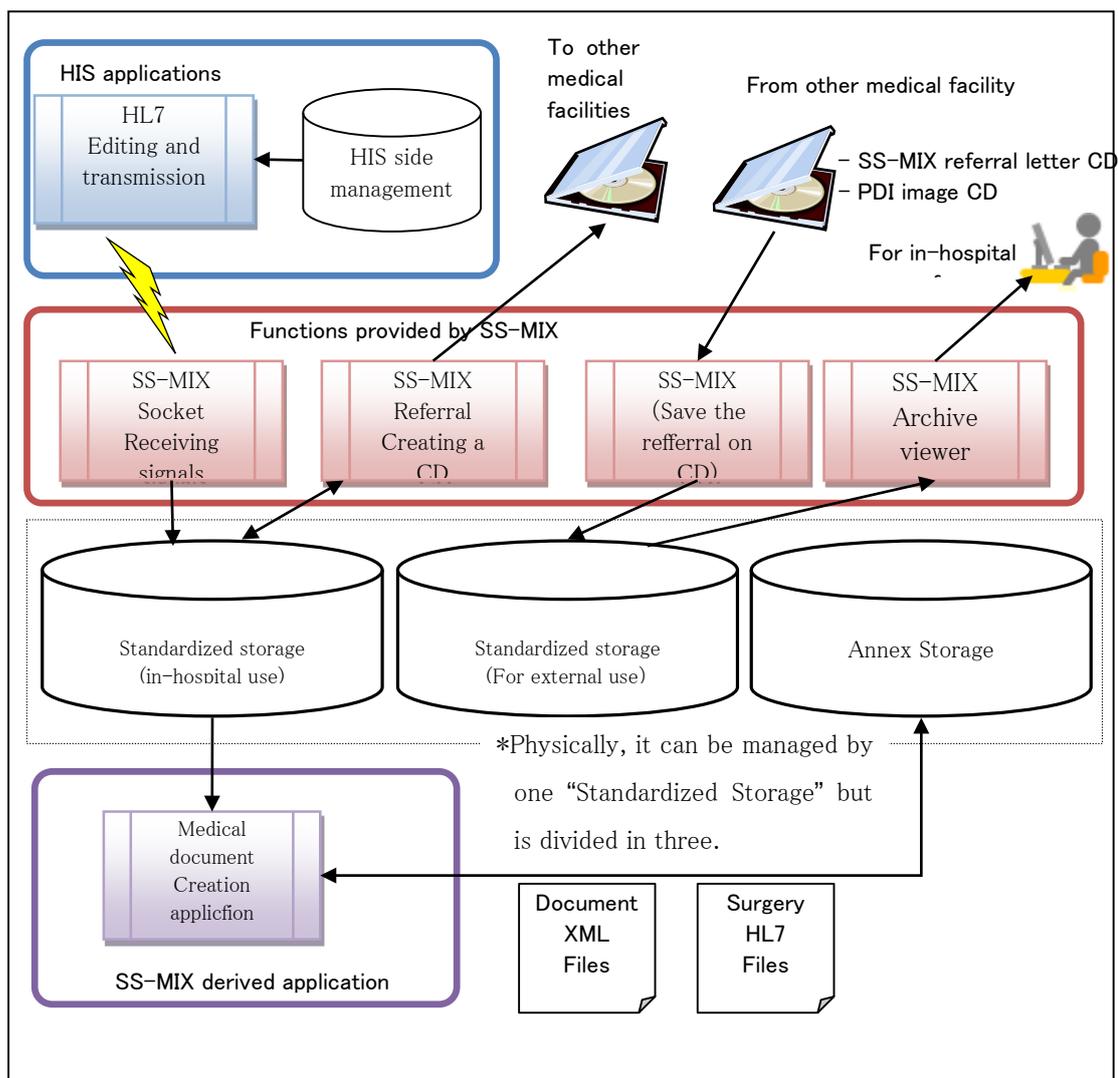


Figure 4.4-1 Example of application of “Annex Storage”1

(1) Functional description

This example has three storages including the “Annex Storage” and manages them by setting the root folder separately in different servers and directories.

The reason is as below.

- ① The “Standardized Storage” (for external use) should be managed in one file folder along with the “Standardized Storage” (for in-house use) but it can not be guaranteed that it will be referred with no exception because data brought from the outside of the medical facility is very large, due to DICOM examination images contained in data as well as it was created by other medical facility (vendor). For this reason, weighing on the server capacity and convenience for follow-up studies, we physically isolate it from the “Standardized Storage” (for in-hospital use).

Another reason is the ease of management as the archive viewer is the only application that refers to data from the outside of the medical facility.

- ② Medical document creation application is a SS-MIX derivation application. While referring patient's basic information, prescriptions and test results managed by the "Standardized Storage", it edits, registers, modifies, circulates, and prints certificates and other medical documents using document templates. Although data being managed is guaranteed by the system and in XML data defined uniformly in the medical facility, it is not recognized as a data file in the medical standard format. Therefore, it is stored in the "Annex Storage".

As such applications increasingly will be introduced in the future, the types of non-standardized data that should be managed will also increase. The second and third "Annex Storage"s are expected to be established in such environment.

- (2) "Annex Storage" structure that the "medical word processing application" builds

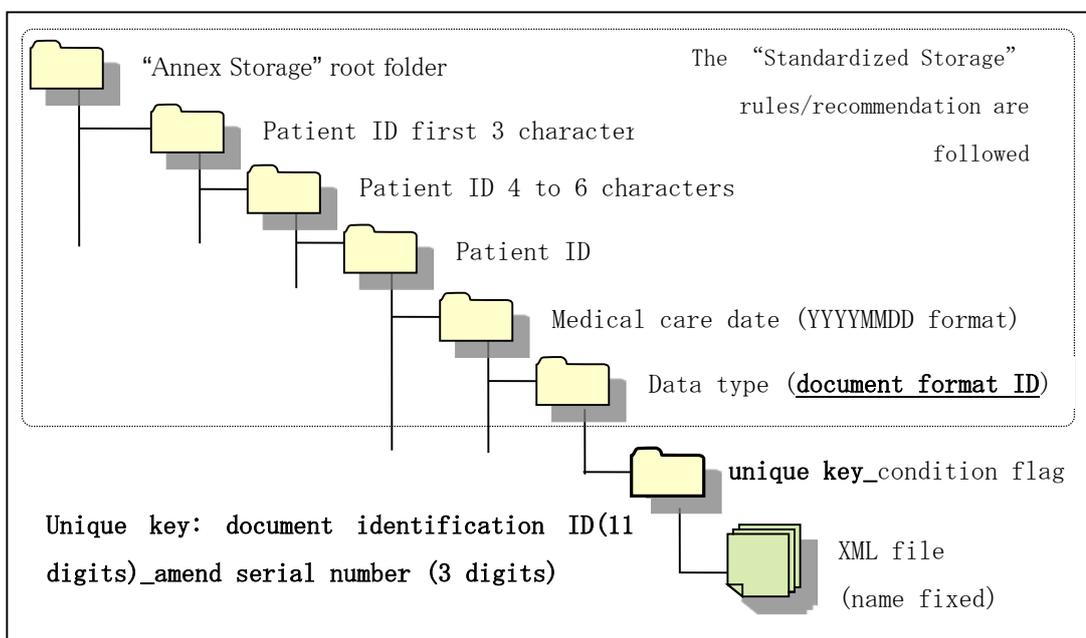


Figure 4.4-2 Typical construction of "Annex Storage"2

- ① Document format ID

It is called 'template ID' in such a system, which is uniquely defined for each of the document formats (=XML data format), such as "XXX insurer's certificate", "adverse event", "geriatric gerontological total function evaluation".

- ② Document identification ID

It is the number that identifies a created document uniquely, and corresponds to the order No.

In this example, the storing file is a file described in XML, and its name is a fixed one for any document. Usually, it is recommended that a file name including 'patient ID', and "medical care date" is set for it so that the storing folder can be identified even by the file itself.

5 Rules for referring to the “Standardized Storage” and “Annex Storage” from the outside
In SS-MIX, the portable media called CD is utilized, and the community healthcare coordination in an offline environment has been promoted. However, today the issues about the costs and security which were initial concerns have been solved along with the prevalent network infrastructures and the advanced technologies, and the examples in practice responding to the needs for community healthcare coordination by network access are emerging one after another.

Here, from the perspective of networking, we describe the rules to comply with and the methods to use for referring to the information of the “Standardized Storage” and “Annex Storage” outside of the relevant medical institution and sending it to other medical institutions electronically.

5.1 Ensuring security

When it is accessed from the outside, the security shall be ensured by a user.

5.2 Means of public disclosure

As the “Standardized Storage” and “Annex Storage” are managed by using the folder file structure of the file management system in the computer operation system itself, and the applications provided in SS-MIX are created on the assumption that they employ Windows OS.

If it is a client that runs on Windows OS, it is the easiest to use the method of accessing through the shared folder (¥¥server¥ share) to refer to the “Standardized Storage” and “Annex Storage”, but, in terms of ensuring the security for public disclosure, creating an application using this method is not allowed. Instead of this, the method of building Web service to retrieve data is specified here.

(1) Request (request)

The data that constitute the hierarchical structure of the “Standardized Storage” and “Annex Storage”, i.e. patient ID, medical care date (range), data type, are configured as parameters, and a request for data acquisition is made by HTTP(S)/GET or POST in REST format, or HTTP(S)/SOAP.

(2) Response (response)

Search result data based on the above query conditions are retrieved. The formats as below are assumed for the data here.

- ① Structured data model (XML) in which the query result is embedded
- ② File itself stored in the “Standardized Storage” and “Annex Storage”

(3) Procedures of request (request) and response (response)

- ① When HTTP(S)/GET in REST format or POST is employed

On the request (request) side and response (response) side, the defined items of request and response are shared, and the access system is implemented for each.

- ② When HTTP(S)/SOAP is employed

WSDL is made, and, based on this WSDL, the request (request) side and response (response) side both implement each access system.

(4) User Authentication

Original user interfaces or functions provided by Web service are used.

5.3 System configuration for the public disclosure method by Web service

The configurations for the disclosing/viewing the “Standardized Storage” and “Annex Storage” by Web service are indicated as follows.

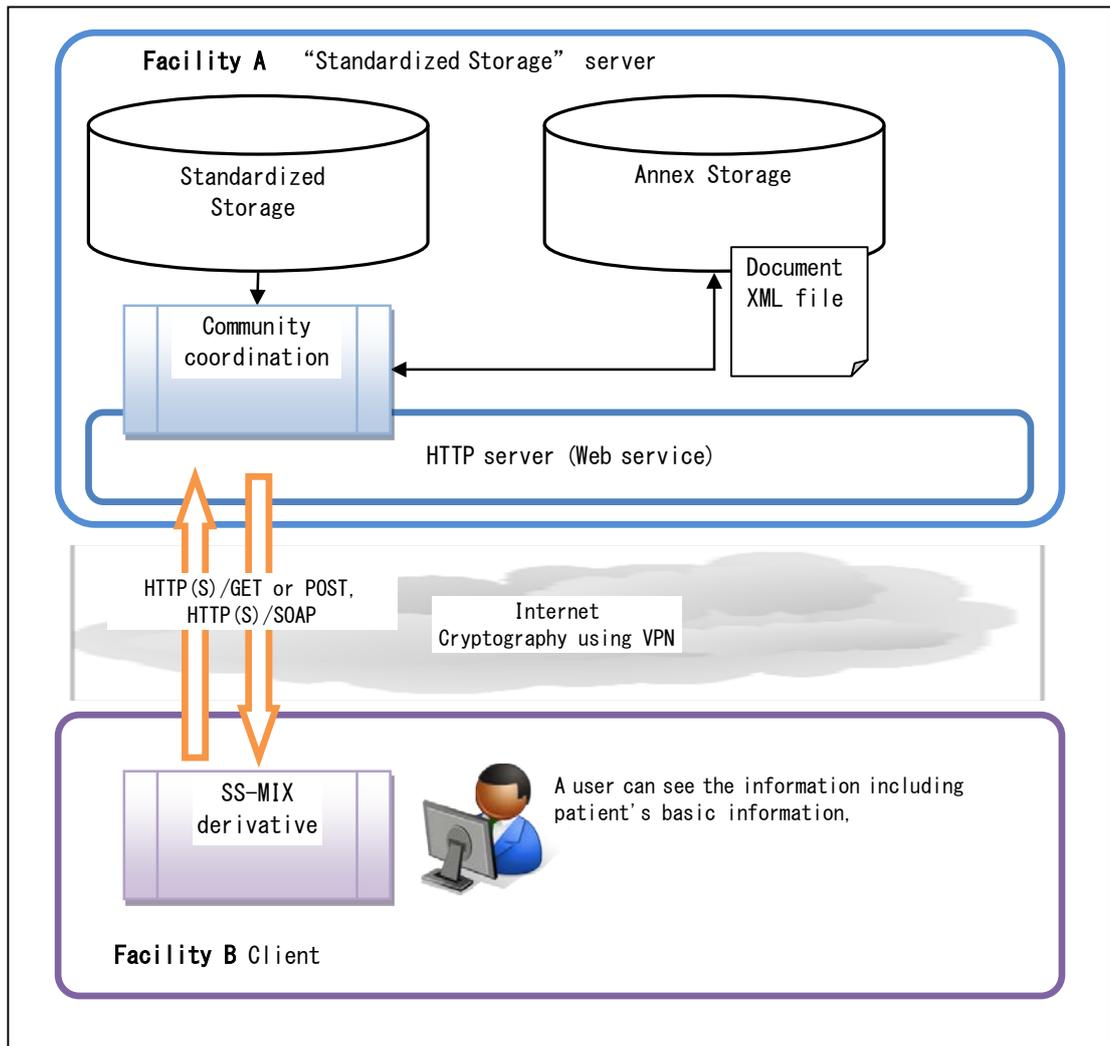


Figure 5.3-1 Example of public disclosure by Web service1

(1) System and function configuration

By building Web service on the server side, it is made possible to see data from the client-side external medical institution under the secure environment. If it assumed that Web is accessed from a client, it is impossible that the problem of access obstruction by setting a firewall etc. will occur, since the common HTTP (port 80) communication or HTTPS (port 443) communication is utilized.

(2) Example of Web interface

In SS-MIX2, based on the rules above, the Web service method by HTTP(S)/SOAP for accessing the “Standardized Storage” is provided. The example of its implementation here is as follows.

① GetPatientInfo

The named patient's basic information data model is retrieved.

② GetOrderList

By specifying the patient ID and medical care date range, the information data model on the relevant prescription and specimen examination result is retrieved.

③ GetKentaiMatrix

The Matrix Table data model of specimen examination is retrieved.

Refer to the aforesaid appendix “SS-MIX2 Standardized Storage Data Cooperation Specification” for other methods than the above and the details on implementation. In the specification, only HTTP(S)/SOAP is mentioned, but if HTTP/GET or POST is used, you have only to replace the items described in the specification with the items of request and response.

6 Conclusion

This document is intended to simply explain the contents specified in SS-MIX, related specifications, their usages etc., to make it easier for many people involved in hospital information systems to understand, build up, and utilize the "SS-MIX Standardized Storage".

Therefore, many parts are omitted to give as simple a description as possible with an emphasis on clearness, so a user needs to see the related specification if needed.

This document was created as carefully as possible by a voluntary group of SS-MIX Promotion Consortium, but if there is anything inconsistent in the specification related with this document, that specification will prevail.

In addition, the builder is responsible for whether the "SS-MIX Standardized Storage" built in reference to this document complies with the related standard specification, but please inquire the following about the contents of this document and SS-MIX.

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