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Trends in health information and communication standards in Japan

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Abstract

　Japan has adopted the universal health insurance system, in which a detailed, single list of fee points is used to evaluate every claim, regardless of type of insurance. The great success of "Rececom" (i.e., an abbreviation for "receipt computer") in managing electronic medical claims, which was developed ahead of the world, may also have represented a significant factor in hindering the spread of electronic medical records systems in the personal computer era. Over time, departmental information systems became linked to computerized provider order entry systems, and data exchange over networks became practical. Nevertheless, interoperability between medical information systems became a problem that was impossible to ignore. In the 1980s, a non-profit organization, HL7 International, was established in the United States to create and disseminate international standards for medical information systems. Subsequently, the Japanese Association of Healthcare Information Systems Industry (JAHIS) was established in 1994, and the Association for Medical Informatics and JAHIS founded the HL7 Japan in 1998. JAHIS and HL7 Japan have since led the development of medical information standards in Japan. In 2001, the Healthcare Information System Review Committee announced a "Grand Design for computerization in the medical field," and MHLW promoted the spread of electronic medical record systems and the development of medical information standards. HELICS, which is an incorporated association of academic societies and industries involved in the provision of health information, was established in 2007. HELICS evaluates proposal to determine whether they should be accepted as proposals for the national standards in Japan. Specific health checkups and specific health guidance are an initiative unique to Japan, drawing worldwide attention as a measure to counter lifestyle-related diseases that are increasing in developed countries. The HL7 CDA document specification is available regarding specific health checkups, and checkup institutions must create and submit checkup reports that conform to the defined specification. The Pharmaceuticals and Medical Devices Agency (PMDA) has three responsibilities: "Relief Service for Adverse Health Effects," "Review," and "Post-marketing Safety Measures." To achieve efficient review and cross-sectional analysis, PMDA requires clinical trial data to be submitted in accordance with the Clinical Data Interchange Standards Consortium (CDISC) standard. Consistent with HELICS proposals, standardization will be promoted principally in accordance with HL7 V2.x and CDA. In addition, the Fast Healthcare Interoperability Resources may be used to develop new medical applications in areas not profiled in these HL7 2.x and CDA related standards in Japan.

keywords: Medical Information Standard, HL 7, FHIR, CDA, DICOM, HELICS

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I. Health care insurance in Japan

Japan has the Universal Health Insurance system, in which the insured person pays a portion of his/her medical fees [1]. Healthcare organizations claim fees for medical services provided. Uniquely, in Japan, a detailed, single list of fee points is used to evaluate every claim, and a defined price is paid in accordance with detailed rules. The list of fee points includes "basic medical examination fees" (e.g., a first visit, revisits, and inpatient dietetic treatment) and "fees for specially listed medical services" (e.g., guidance, in-home medical care, tests, diagnostic imaging, medication, injections, rehabilitation, specialized psychiatric therapy, treatment, surgery, anesthesia, and radiation therapy) [2]. In this fee-for-service system, healthcare providers claim the total fees by multiplying the number of times each procedure was performed by the number of points specified in the fee points list [3]. For example, when a patient is hospitalized for surgery, the following fees are charged: a first-visit fee, an inpatient dietetic treatment fee proportional to the period of hospitalization, a surgery fee, test fees, and diagnostic imaging and medication fees. No extra fees can be charged. Detailed rules impose upper limits on the numbers of medications, injections, and diagnostic imaging procedures that are permitted. The fee list is typically revised at 2-year intervals by the Ministry of Health, Labour and Welfare (MHLW), following discussions with the Central Social Medical Insurance Council (Chuikyo), which has been established by the MHLW. Chuikyo stakeholders include: representatives of doctors, dentists, and pharmacists (medical care providers); representatives of insurers, insured persons, and examination and payment organizations; and public members who engage and coordinate the work of committee members, verify fee list provisions, and are responsible for public accountability.

Over time, the comprehensive evaluation of inpatient medical care (principally, chronic care) has been expanded to include acute inpatient care. A Diagnostic Procedures Combination (DPC) [4] was trialed in 1998, introduced in special function hospitals in 2003, and has increasingly been expanded to include 1,730 hospitals by 2018. A Diagnosis Related Group, modeled on the United States system, determines medical fees in terms of diagnoses. The DPC is a per-diem system coded using Major Diagnostic Categories, which refer to the diagnoses in which most medical resources are invested during hospitalization. The Major Diagnostic Categories list is based on the International Classification of Diseases (ICD)-10 classification, and 18 major diagnostic groups are defined. The DPC includes more than 2,000 categories, classified [5] (via decision trees) using combinations of Major Diagnostic Categories,

classification codes, age, bodyweight, the Japan Coma Scale (a grading system used to evaluate consciousness), surgical procedures, and medical treatments. For statistical purposes, each fee claim must include the diagnosis in which the most resources were invested. In addition, it must also include the principal disease (as clinically determined), the disease that triggered/was the cause of hospitalization, comorbidities at the time of admission, and comorbidities that developed during hospitalization. To facilitate DPC coding, all electronic medical records (EMRs) use the ICD10-based Standard Disease Code Master for Electronic Medical Records (HS005). Each EMR features an entry screen for the mapping of DPC-recognized diseases, based on the diagnostic history.

As noted above, the DPC is a per-diem system, not a complete comprehensive payment system. To encourage shorter hospitalization periods, fees are reduced as hospitalization is prolonged, and hospital performance is evaluated by calculating efficiency coefficients. The DPC has two components, in accordance with which a healthcare provider claims fees as reimbursements for medical services provided during hospitalization. The first component is an inclusive payment calculated as a per-diem fee for each diagnosis, which decreases as the hospital stay is prolonged, the second component is a partial fee-for-service system that covers drug prescriptions at the time of discharge, certain examinations/imaging procedures, expensive treatments, surgery, anesthesia, and rehabilitation. A specific hospitalization period is defined for each diagnostic group. If the length of hospitalization exceeds the defined period, the hospitalization fee for the extra days is calculated using the partial fee-for-service system based on the official list of medical fees, as described above.

Thus, in Japan, there is a single national list of official medical fees based on a standard code. In the 1950s, a "Rececom" (i.e., an abbreviation for "receipt computer") to manage medical claims was developed using COBOL. By the 1970s, this type of computer was used by 70% of healthcare providers nationwide, as the device greatly reduced the volume of office work. Disease and medication codes were established early, and these codes were used by all medical institutions and insurers. Thus, there were limited developments in ontology to allow mapping between different terminologies. Prior to the introduction of personal computers, Rececoms were extremely popular, as they were both comprehensive and efficient. Small healthcare providers could not afford to adopt EMR systems, even in the era of personal computers. This delayed modern computerization and the rationalization of medical information standards.

II. History of medical information standards in Japan

The 1960s featured medical accounting systems, while the 1970s featured computerized provider order entry systems (CPOEs) and laboratory information systems. In 1987, a non-profit organization, Health Level Seven (HL7) International, was established in the United States to create and disseminate international standards for medical information systems. The Japanese Association of Healthcare Information Systems Industry (JAHIS) [6] was established in 1994, with the aim of improving health by enhancing health and welfare information systems, ensuring the quality and safety of such systems, and developing and promoting medical information standards and guidelines. The JAHIS thus developed the Japanese medical information systems and standards.

In the 1990s, although CPOEs remained popular, EMRs were introduced and overlaid onto legacy CPOE systems by large medical institutions, in order to manage records so that fees were appropriately claimed. These EMRs were not based on fundamental principles of medical practice or medical concepts. At around this time, departmental information systems became linked to CPOEs, and data exchange over networks became practical. On the other hand, interoperability between medical information systems became a problem that could no longer be ignored. In addition, the various medical information systems worldwide did not intercommunicate, as both healthcare systems and the medical terms used varied among countries. It was essential for Japan to develop a set of Japanese specific specifications that follow the standards established by HL7 International. Therefore, in 1998, key members of the Japan Association for Medical Informatics (JAMI) and JAHIS founded the HL7 Japan [7]. In 1999, JAHIS published a Japanese edition of the HL7 laboratory data standard. In addition, "Guidelines on the electronic preservation of medical records and some notes/reports that their preservation is stipulated by the law" [8] were published during that year, which allowed the preservation of medical records in digital format, provided that three principles (authenticity/integrity, readability, and safe storage/availability) were followed by the healthcare provider. These guidelines continue to serve as the legal basis of EMRs in Japan.

In 2001, the Healthcare Information System Review Committee announced a "Grand Design for computerization in the medical field" [9]. An optimal healthcare system should leverage information technology. Accordingly, discussions on the implementation of computerization then gave rise to an action plan. The first focus was the computerization of fee claims via the standardization of medical terms and codes. Next, methods to facilitate the networking of healthcare providers were sought, thereby promoting regional health networks. In the third stage, health data required for research and policymaking were made available. Finally, the use of health information to support evidence-based medicine was emphasized. The aim of the action plan was to establish EMR systems in over 60% of hospitals, covering more than 400 beds, nationwide by 2006 [10].

JAHIS published a Protocol for medication data communication in 2001 [11] and a Protocol for radiology data communication in 2003 [12], both of which were Japanese editions of the HL7 standards. In the United States, HL7 International issued the HL7 2.5 Standard in 2002, which was adopted as the ISO/HL7 standards in 2009 [13] and the HL7 V3 Normative Edition in 2005, both of which continue to be widely used in Japan.

The MHLW promoted standardized medical information exchange among regional healthcare providers, under a "Ministry Project to Promote Standardized Healthcare Information Exchange" that commenced in 2004. A Standardized Structured Medical Information eXchange (SS-MIX) [14] was used to store health information and enable exchange among healthcare providers. SS-MIX stipulates "storage rules" for the management of medical information in several structured directories, and a "guideline for implementation" ensuring that HL7 2.x messages can be exchanged with the correct semantic meanings. At that time, SS-MIX stored only HL7 2.x messages; later, storage was expanded to support HL7 Clinical Document Architecture (CDA) documents and Digital Imaging and Communications in Medicine (DICOM) files.

In 2007, the MHLW established a Healthcare Information Standardization Committee to flexibly formulate and adopt medical information standards. The Committee evaluates whether standards proposed by the HEaLth Information and Communication Standards Organization [15] (HELICS, see below) should be adopted as national standards. The MHLW notifies healthcare providers of proposals adopted as national standards, and encourages the use of such standards.

Since 2008, all medical insurers have been required to provide Specific Health Checkups and Specific Health Guidance [16] for all insured persons and their dependents aged 40 to 74 years. Specific Health Checkups are conducted annually, with a focus on visceral fat obesity to prevent lifestyle diseases that cause approximately 60% of all deaths in Japan [17]. During Specific Health Guidance sessions, public health nurses and registered dietitians review the lifestyles and habits of those determined to be at high risk of lifestyle diseases, based on the results of their health checkups.

Patients receive information regarding the prevention of lifestyle diseases through improvements in lifestyle. The health checkup items are specified in the Standard for Implementation of Specific Health Checkups and Specific Health Guidance (MHLW Ministerial Ordinance No. 157, Article 1 [18]). The HL7 CDA document specification is available [19] regarding specific health checkups; checkup institutions must create and submit checkup reports that conform to the defined specification.

In 2010, the following proposals were adopted as national standards by the MHLW: the Standard Master for Pharmaceutical Products (HOT reference code) (HS001); the ICD10-based Standard Disease Code Master for Electronic Medical Records (HS005); a Patient Referral Document and a Clinical Data Document (HS007); a Referral Document (HS008); an IHE Portable Data for Images Integration Profile, and its Application Guideline (HS009); a DICOM (HS011); the JAHIS Protocol for Clinical Laboratory Data Communication (HS012); and ISO 22077-1:2015 Health Informatics (Medical Waveform Format) Part 1: Encoding Rules Ver. 1 (HS028). Subsequently, the standard proposals of HELICS have been sequentially adopted as national standards (Table 1) [20].

In 2018, the Committee on Health Information Collaboration Infrastructure published a draft roadmap for establishment of nationwide health information exchange networks

Table 1   The List of proposed health information and communication standards at HELICS

Registration #	Year of Adoption	Year of Adoption	Name of Specification	Organization
HS001	2002	2003	Standard Master for Pharmaceutical Products (HOT reference code)	Medical Information System Development Center
HS005	2004	2004	ICD10 Based Standard Disease Code Master for Electronic Medical Records	Medical Information System Development Center
HS007	2006	2007	Patient Referral Document and Clinical Data Document	HL7 Japan
HS008	2007	2008	Referral Document	HL7 Japan
HS009	2008	2008	IHE: PDI (Portable Data for Images) Integration Profile, and Its Application Guidelines	Japan Association for Medical Informatics
HS011	2009	2010	Digital Imaging and Communications in Medicine (DICOM) (revised from HS004)	Japan Medical Imaging and Radiological Systems Industries Association
HS012	2009	2010	The JAHIS Protocol for Clinical Laboratory Data Communication (revised from HS002)	Japanese Association of Healthcare Information Systems Industry
HS013	2009	2010	Standard Dental Disease Code Master	Medical Information System Development Center
HS014	2009	2011	Laboratory Test Code Master	Medical Information System Development Center
HS016	2011	2011	The JAHIS Protocol for Radiology Data Communication	Japanese Association of Healthcare Information Systems Industry
HS017	2011	2011	Interoperability Guideline for Scheduling, Accounting, and Radiation Logging between HIS, RIS, PACS, and Modality (JJ1017 Guideline)	Japanese Society of Radiological Technology
HS022	2013	2014	The JAHIS Protocol for Prescription Data Communication	Japanese Association of Healthcare Information Systems Industry
HS024	2014	2016	Standard Terminology for Nursing Observation and Actions	Medical Information System Development Center
HS026	2015	2016	"SS-MIX2 Storage" Specification and Guidelines for Implementation	Japan Association for Medical Informatics
HS027	2016	2016	Standard administration (frequency and timing) codes for prescription and injection orders on the computerized physician's order entry system for medical treatment	Japan Association for Medical Informatics
HS028	2016	2016	ISO 22077-1:2015 Health informatics -- Medical waveform format -- Part 1: Encoding rules (Ver. 1) (revised from HS010)	Medical Information System Development Center
HS029	2016	2019	Basic Outcome Master for Patient state	Japanese Society for Clinical Pathway
HS030	2018	2019	Retrieve Form for Data Capture Integration Profile (RFD)	Integrating the Healthcare Enterprise Japan
HS031	2016	2017	The implementation specification of the infrastructure for healthcare information exchange (revised from HS023 and HS025)	Integrating the Healthcare Enterprise Japan
HS032	2018	2019	Standard Specification for Discharge Summary, based on HL7 CDA Release 2	HL7 Japan
HS033	2018	2018	Standardized dental formula code specification	Medical Information System Development Center

and services [21]. In terms of the health information to be shared, no national standards have yet been established for radiology or pathology reports, nursing summaries, or general medical checkup reports [22]. However, in 2018, JAHIS published a specification for pathology/clinical cell DICOM imaging data (ver. 3.0) [23]; in 2015, JAHIS published a structure for reports on pathological diagnoses (ver. 1.0) [24]; and, in 2019, JAHIS published a specification for checkup reports (ver. 2.0) [25].

III. HELICS: The HEaLth Information and Communication Standards Organization

1. Mission of HELICS

HELICS is an incorporated association of academic societies and industries involved in the provision of health information: the Medical Information System Development Center (MEDIS) [26]; the Japan Radiological Society [27]; the JAMI [28]; the Japan Medical Imaging and Radiological Systems Industries Association (JIRA) [29]; the Japanese Society of Radiological Technology (JSRT) [30]; the Japanese Association of Healthcare Information System Industries (JAHIS); Integrating the Healthcare Enterprise Japan (IHE-J) [31]; the Japanese Society for Radiation Oncology [32]; GS1 Healthcare Japan [33]; and HL7 Japan. HELICS oversees four principal issues:

1) Development of national standards

When a candidate national standard is submitted for review, HELICS checks its completeness and its consistency with domestic and foreign standards, as well as the business viability of any involved organization. HELICS decides whether the standard should be disseminated in the healthcare field. If HELICS concludes that the standard should become a national standard, the proposal is adopted.

2) Educational campaigns

HELICS publicizes proposed standards and holds seminars to report on standardization activities.

3) Assistance with standardization

HELICS advises organizations that are involved in standardization, as required. The organization that submits a proposal may not necessarily be the organization that develops the standard; an organization that would benefit from standardization may submit a proposal. HELICS works with and advises relevant organizations to ensure maintenance of the standard and the business health of the organizations.

4) Support for international activities

HELICS supports organizations that are participating in the development of international standards, in order to propose specific Japanese requirements to be reflected in such standards, and coordinates these efforts with those of other affected organizations.

The proposal of a national standard by HELICS is simply a recommendation. The MHLW encourages HELICS to create stakeholder agreement regarding health information standards. Typically, MHLW adopts standards proposed by HELICS as national standards. However, these proposals are only recommendations; if the use of a standard is obligatory, MHLW will provide a formal notice. For example, in the "Instructions for entry of medical claims" [34], it is stated that the disease name should generally be coded using "the code system for the disease used on the claim made online or via optical disc" [35]. This text forms part of the notice entitled, "Regarding matters and methods established by MHLW for the medical fee claim using electronic information processing and the standards established by MHLW for requests for medical fees made on optical discs, etc." [36]. Currently, the website of the MHLW Health Insurance Bureau contains the master list of disease names [37]. The Social Insurance Medical Fee Payment Fund formed a working group to revise the medical terms of the ICD10-Based Standard Disease Code Master for Electronic Medical Records (HS005), developed by MEDIS. The working group performed a detailed exploration to determine how clinical concepts were associated with ICD-10 codes, after which the contents of both disease masters (the versions of the MHLW Health Insurance Bureau and MEDIS) were standardized. The only difference is that the disease master of the Health Insurance Bureau contains information regarding medical fee claims, such as whether a disease name is used to derive a fee for treatment of a specific disease, or to derive a consulting fee for an intractable disease treated on an outpatient basis. The HS013 master list contains the names of diseases peculiar to the dental field and the classification of the International Classification of Dentistry and Stomatology, Third Edition. When submitting a claim to the MHLW, a dentist enters the disease name in the EMR using the HS013 standard.

2. Principal proposals adopted by HELICS
1) HS001: Standard Master for Pharmaceutical Products (HOT reference code)

Several codes are used for pharmaceutical products: the MHLW Code (Drug Code), the "individual drug code" (YJ code), and the Japanese Article Numbering code. Previously, no unified code was used to semi-permanently identify medicines when their details were entered into EMRs and databases. MEDIS developed the Standard Master for Pharmaceutical Products (HS001), which assigns a unique

13-digit number (HOT code) to all drugs and maps the codes to those of the four code systems described below. The drug price standard covers all medicines approved by the "Pharmaceutical and Medical Devices Act" [38], and defines the prices that the National Health Insurance scheme will pay. The MHLW manages the drug price standard, which features 12-digit alphanumeric drug codes, also termed "MHLW (Drug) Codes." The drug price standard features two lists: one of brand (trade) names and one of generic names. In the list of brand (trade) names, each product is assigned a code. In the list of generic names, regardless of the availability of multiple products, a single code is assigned to all generics with the same ingredients, dosage forms, and specifications. Drugs not officially recognized by the MHLW are assigned single codes (i.e., YJ codes) with generic names, regardless of whether several products are available. Thus, the YJ code is a 12-digit code similar to those of the generic drug price list. However, YJ codes are unique, so that each product with a generic name is distinguished. The "receipt computer processing system code" is a nine-digit code designating drugs for which prices are listed. A healthcare organization submits electronic receipts (claims) to the examination/payment organization. The international article number of the Japan code (Japanese Article Numbering code) is a universal product identification code used for logistics. GS1 (an international not-for-profit organization that promotes the standardization of business communication) and the Japanese branch office of the Distribution System Research Institute manage the Japanese Article Numbering code. Using the Standard Master for Pharmaceutical Products (HS001), drug prices, prescriptions recorded in EMRs, and drug logistics are integrated.

2) HS007: Patient Referral and Clinical Data Document

This standard was designed by HL7 Japan. Important medical information is summarized and provided to patients to ensure that medical services are both appropriate and uninterrupted when patients visit different medical providers. HS007 is an HL7 CDA R2-compliant standard that provides electronic medical information linked to external multimedia files, such as medical images and waveform data. Detailed specifications are provided in terms of medical information, Portable Data for Imaging, the digital signature specified (by JAHIS) for CDA documents, and the protocol specified (by JAHIS) for CDA document encryption. There was initially a concern that enforcing structured entry would burden healthcare professionals. Thus, the standard does not mandate healthcare professionals to fulfill the requirements of the CDA R2 Clinical Statement (level 3), and natural text is often allowed.

3) HS008: Referral Document

HS007 provides comprehensive medical information that allows patients to receive continuing medical services in different institutions. Compared to HS007, HS008 is a lightweight standard that simply introduces patients of one medical institution to another institution. However, information concerning referral (source, medical institution, and healthcare professional) is added.

4) HS009: IHE: PDI (Portable Data for Images) Integration Profile and Application Guideline, and HS011: Digital Imaging and Communications in Medicine (DICOM)

HS011 was developed by JIRA. The DICOM Standards Committee and MITA are responsible for the evaluation and management of all DICOM standards. Any professional can suggest a modification of a standard by communicating directly with the DICOM Standards Committee or JIRA. JAMI extracted and summarized the IHE specifications into HS009 specifications, by integrating the methods used to exchange medical information (including images) described in Chapters 1, 2, and 15 of Volume 1 (RAD TF-1) of "Integration Profiles" and Volume 3 (RAD TF-3) (the Transactions [Continued] of "IHE Radiology [RAD] Technical Framework," review 18.0). These profiles define the persons involved and the methods they must use when transferring DICOM images (as specified by HS011) to portable media, such as CDs and DVDs. Furthermore, the profiles specify the arrangement of DICOM image files in directories (DICOMDIRs) and methods to index the files.

5) HS012: The JAHIS Protocol for Clinical Laboratory Data Communication

HS012 concerns the exchange of clinical laboratory data derived in the same or different healthcare settings, and laboratory automation (analyzers and sample transport systems). The protocol assumes a hospital information system, laboratory information system, and laboratory automation system as actors and specifies the content of HL7 2.x messages exchanged among these actors using the HS014 standard as the code master for the description of laboratory requests and results.

6) HS014: Laboratory Test Code Master

When the same laboratory test codes are used by departmental systems and the groups that bill medical fees, information management is uniform, and the maintenance load of the laboratory master may be reduced. MEDIS maintains a master code that has been developed since the 1960s in cooperation with the Committee of the Japanese Society of Laboratory Medicine [39] and the Health Insurance Claims

Review and Reimbursement Services [40]. The master maps to the JLAC10 (clinical examination item classification code, 10th revised edition) code table maintained by the Japan Society for Laboratory Medicine [41]. In addition, it also maps to the medical practice master code of the Health Insurance Claims Review and Reimbursement Services. In the JLAC10 code table, laboratory items are defined by 17-digit codes that combine five elements (analyte [5 digits]/identification [4 digits]/material [3 digits]/measurement method [3 digits]/result identification [2 digits]).

7) HS016: The JAHIS Protocol for Radiology Data Communication

HS016 defines the contents of HL7 2.x messages exchanged between Hospital Information Systems, Radiology Information Systems, Picture Archiving and Communication Systems, and Report Systems. The messages include radiological examination requests, radiological examination notices, patient arrival notices, radiological examination reports, and communications regarding patient information management (e.g., patient enquiries and notices to patients). HS016 uses the JJ1017 code as standard code in messages that are compliant with HS016.

8) HS017: Interoperability Guideline for Scheduling, Accounting, and Radiation Logging between HIS, RIS, PACS, and Modality (JJ1017 Guideline)

JJ1017 is an acronym derived from the title of the relevant committee, as follows: "J" AHIS, "J" IRA, DICOM supplement "10" (MWM: Modality Worklist Management), and DICOM supplement "17" (MPPS: Modality Performed Procedure Step). JJ1017 develops the terminology for radiation appointments, accounting, and records. This terminology facilitates integration with CPOEs, accounting systems, Picture Archiving and Communication Systems, Radiology Information Systems, and other modalities.

9) HS022: The JAHIS Protocol for Prescription Data Communication

HS022 defines the contents of exchanged HL7 2.x messages that concern medication requests, dispensing, and administration. These messages are read by hospital information, drug department, nursing support, and medical accounting systems. HS022 uses the HS001 drug code and the HS027 dosage/route/site code.

10) HS024: Standard Terminology for Nursing Observation and Actions

HS024 concerns the terminology of nursing records (i.e., actions and observations). Nursing actions feature a four-level structure: comprehensive and purpose-specific classifications, specific actions, modifiers of the situation, and method of action. Nursing observations consist of items and results. HS014 is used to select nursing actions and observations, and also to input them into the screens of electronic vital sign charts, lists of nursing instructions, and clinical pathways.

11) HS026: SS-MIX2 Storage Specification and Guidelines for Implementation

HS026 specifies how HL7 2.x messages from a medical information system should be archived to external storage. Both the standardized hierarchical structure and filename conventions of HL7 2.x messages are considered. HL7 2.x messages include those containing general patient information, allergy data, disease names, dietary observations, medications, pharmacy/treatment considerations, observations, imaging orders, endoscopy results, and physiological data. Since the adoption of HS026, SS-MIX has added "extended storage" to define how documents other than HL7 V2.x messages should be stored (e.g., DICOM, HL7 CDA, and PDF data).

12) HS027: Standard Administration (Frequency and Timing) Code of Prescription and Injection Order of the Computerized Physician Order Entry System for Medical Treatment

HS027 contains standard codes describing dose number/frequency/timing (oral or injected), based on the "Standard Administration Glossary" [42] developed by the Japan Pharmaceutical Association [43] and the Japan Society of Hospital Pharmacists [44].

13) HS028: ISO 22077-1:2015 Health Informatics (Medical Waveform Format) Part 1: Encoding Rules

HS028 specifies how medical waveforms (electrocardiograms, electroencephalograms, blood pressure waveforms, and any waveforms that change over time) should be described.

14) HS029: Basic Outcome Master for Patient Status

HS029 collects terms used in the clinical description and classifies them in a hierarchical manner. These include the daily clinical goals, the condition to be achieved (i.e., outcome), and the evaluation criteria (i.e., observational items and values). Outcomes are classified into four broad categories: "patient status," "knowledge/education/understanding," "motion/daily living activity/rehabilitation," and "other." Organ and function are used to subdivide the "knowledge/education/understanding" and "motion/daily living activity/rehabilitation" categories, and outcomes and

observational items are classified at lower levels in these categories. The observational items conform to HS024. HS029 is used to display or enter daily goals and the evaluation criteria used during clinical pathway screening.

15) HS031: Implementation Specification of the Infrastructure for Healthcare Information Exchange

HS031 consists of certain frameworks, selected from among Integrating the Healthcare Enterprise technical frameworks, that must be used when sharing patient identity and medical information among healthcare providers within regional health networks. HS031 discusses the following frameworks: Patient Identifier Cross-Referencing (PIX), Patient Identifier Cross-Reference HL7 V3 (PIX v3), Patient Demographics Query (PDQ), Patient Demographics Query HL7 V3 (PDQV3), Cross-Enterprise Document Sharing (XDS.b), Cross-Enterprise Document Sharing for Imaging (XDS-I.b), Cross-Community Access (XCA), Cross-Community Access for Imaging (XCA-I), Consistent Time (CT), Audit Trail and Node Authentication (ATNA), Cross-Enterprise Document Reliable Interchange (XDR), and Cross-Community Patient Discovery (XCPD). Regional health networks are encouraged to implement these standards.

16) HS032: Standard Specification for Discharge Summary Based on HL7 CDA Release 2

The Japan Society of Health Information Management [45], the Japanese Association of POS Medicine, and the Japan Association for Medical Informatics established the HS032 standard, which standardizes sections of the discharge summary and enables the electronic exchange of these sections. Because discharge summaries are often read by medical professionals, the HS032 standards were defined in accordance with HL7 CDA R2, and places an emphasis on readability.

17) HS033: Standardized Dental Formula Code Specification

For EMRs, HS033 standardizes dental formulae and codifies electronically exchanged information. The standard tooth code includes the following features: tooth type (four digits: up/down/left/right and tooth type), treatment status (one digit), location (one digit specifying the part of the tooth that is evaluated), and future plans (three digits).

IV. The Pharmaceuticals and Medical Devices Agency (PMDA)

In 2004, the Pharmaceuticals and Medical Devices Agency (PMDA) [46] was established by law. The PMDA has three responsibilities. The first responsibility, the "Adverse Drug Reaction Relief System," provides prompt relief of drug side effects and infections caused by biological products. The second responsibility, "Review," involves the Agency in continuous evaluation of the quality, efficacy, and safety of pharmaceuticals and medical devices (from clinical trials to approval). The third responsibility, "Post-marketing Safety Measures" requires the Agency to contribute to public health improvement via collection, analysis, and provision of post-marketing safety information. To achieve efficient review and cross-sectional analysis, the PMDA requires clinical trial data to be submitted in accordance with the Clinical Data Interchange Standards Consortium (CDISC) standards. Following a pilot test in 2013, electronic data submission for all clinical trials will become mandatory in April 2020. As of November 2019, a "Data Standards Catalog" [47] lists the standards that may be used when submitting electronic applications. This catalog provides a CDISC Study Data Tabulation Model (SDTM) and an SAS Transport Format (XPT) (data exchange standards for clinical study datasets), and also allows CDISC Controlled Terminology (CT), Medical Dictionary for Regulatory Activities (MedDRA) developed by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH), and World Health Organization (WHO) Drug Dictionary Enhanced (WHO-DD) /WHO Drug Global standard terminologies. The CDISC SDTM and CT were developed independently of the medical information model and controlled terminology that are standard in Japan. Therefore, pharmaceutical companies that submit data to regulatory authorities may be required to convert Japanese terms into CDISC terminology.

V. HL7 Fast Healthcare Interoperability Resources (FHIR)

Although Fast Healthcare Interoperability Resources (FHIR) have been introduced in many countries worldwide, introduction in Japan has been slow. In 2019, JAMI established a Fast Healthcare Interoperability Resources study group, as well as a consortium to explore a "Common Platform for Next-Generation Electronic Healthcare Record Systems" [48]. These groups have begun to identify the requirements of a Japanese-specific profile and applications. Consistent with HELICS proposals, some Japanese standards based on the HL7 CDA have recently been announced. In the near future, standardization will be promoted principally in accordance with HL7 V2.x and CDA. In addition, the Fast Healthcare Interoperability Resources may be used to develop new medical applications in areas not profiled in these HL7 2.x and CDA related standards.

Notably, SNOMED-CT and LOINC are principally employed for FHIR. However, as Japan is not a member of SNOMED International, SNOMED-CT and LOINC are rarely used in Japan. Terminologies specified by HELICS may continue to be used in the near future, and may subsequently be ported to the FHIR CodeSystem and ValueSet using Japan-specific terminologies that reflect the Japanese environment.

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我が国における医療情報規格の動向

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抄録

　日本は保険の種類にかかわらず単一の公定価格を設定した診療報酬点数表にもとづき，診療報酬を決定する制度を採用し，早くから病名や医薬品に関するマスターを策定してきた．世界に先駆けて導入された診療報酬請求に特化したレセコンの成功は，一方で皮肉にもパーソナルコンピュータ時代にあわせた医療情報システム，電子カルテへの移行を妨げた要因とも見做しうる．ネットワーク技術が普及し，部門システムの接続が増えると相互運用性が課題となった．1980年代に米国でHL7協会が設立された時に，我が国では一般社団法人 保健医療福祉情報システム工業会の前身である日本保健医療情報システム工業会，そして日本HL7協会が設立され，我が国における医療情報システムと標準規格の開発を牽引してきた．2001年の保健医療情報分野の情報化にむけてのグランドデザインを契機として我が国における電子カルテ普及と医療情報標準規格の開発の推進がなされた．2007年に一般社団法人医療情報標準化推進協議会（HELICS）が設立された．HELICSは厚生労働省標準規格として認定すべき標準規格を検討し医療情報標準化指針として採択している．HL 7 2.x，HL7 CDA，IHEのプロファイル，DICOM等国際標準規格を取り入れ，日本の事情にあわせた実装ガイドラインが多数公開されている．また，世界的にも注目されている我が国特有の取り組みとして特定健康診査・特定保健指導があり，HL7 CDAを用いたデータ交換規約が発表されている．独立行政法人 医薬品医療機器総合機構（PMDA）は医薬品などの健康被害救済，承認審査，安全対策を担当する規制当局として，CDISC標準を中心とした標準医療情報規格を利用したデータ収集に取り組んでいる．現状ではHL 2.xやCDAを中心とした標準規格が発表されたばかりであるため，当面はこれらの規格と我が国独自の統制用語集を用いたシステム運用が続く．FHIRに関する議論は緒に就いたばかりであり，これまでの標準規格で考慮されていないアプリケーションへの適応や，従来の相互運用性確保に関する資産をFHIRに如何に継承するかの議論がなされることが予想される．

キーワード：Medical Information Standard，HL 7，FHIR，CDA，DICOM，HELICS