Recommended configuration for personal health records by standardized data item sets for diabetes mellitus and associated chronic diseases: A report from Collaborative Initiative by six Japanese Associations

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SPECIAL REPORT

Recommended configuration for personal health records by standardized data item sets for diabetes mellitus and associated chronic diseases: A report from Collaborative Initiative by six Japanese Associations

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Keywords
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ABSTRACT

It is expected that a large amount of data related to diabetes and other chronic diseases will be generated. However, databases constructed without standardized data item sets can be limited in their usefulness. To address this, the Collaborative Committee of Clinical Informatization in Diabetes Mellitus was established in 2011 by the Japan Diabetes Society and Japan Association for Medical Informatics. The committee has developed core item sets and self-management item sets for diabetes mellitus, hypertension, dyslipidemia, and chronic kidney disease in collaboration with the Japanese Society of Hypertension, Japan Atherosclerosis Society, Japanese Society of Nephrology, and Japanese Society of Laboratory Medicine, as well as a mapping table that aligns the self-management item sets with the Japanese standardized codes for laboratory testing. The committee also determined detailed specifications for implementing the four self-management item sets in personal health record (PHR) applications to facilitate risk stratification, the generation of alerts using information and communications technology systems, the avoidance of data input errors, and the generation of reminders to input the self-management item set data. The approach developed by the committee may be useful for combining databases for various purposes (such as for clinical studies, patient education, and electronic medical record systems) and for facilitating collaboration between PHR administrators.

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BACKGROUND AND AIMS

Many databases have been developed to store and generate information about diabetes mellitus and other chronic diseases[1,2], but their subsequent use can be limited by inconsistent data standards, such as the precise sets of data items used, and they may therefore have limited utility beyond their initially defined roles. Recently, there has been a rapid expansion of digitization in clinical practice and research. When appropriate information standards are defined before a new database is created, it may then be possible to reuse the database for other purposes. For example, a database developed for tracking information about patient self-monitoring of diabetes might then be used for clinical research, establishing evidence-based quality indicators, or facilitating regional medical cooperation.

In 2010, the Japan Diabetes Society (JDS) and the Japan Association for Medical Informatics (JAMI) established the Collaborative Committee for Clinical Informatization in Diabetes Mellitus (CCCIDM) to review the digitalization of clinical data about diabetes mellitus. The present article is a report of the work of the committee in collaboration with six Japanese academic associations: the JDS and JAMI, as well as the Japanese Society of Hypertension (JSH), the Japan Atherosclerosis Society (JAS), the Japanese Society of Nephrology (JSN), and the Japanese Society of Laboratory Medicine (JSLM, which participated from 2015). The report introduces the sets of data items established by the committee in 2015 for diabetes mellitus and the associated chronic diseases hypertension, dyslipidemia, and chronic kidney disease (CKD), as well as the committee's recommended data configurations, established in August 2018, for personal health record (PHR) applications, which was the first use of the data sets.

MATERIALS AND METHODS

By the end of 2011, CCCIDM developed a core data item set (CIS) that listed the minimum set of data items necessary for diabetes-related databases. However, the CIS alone could not be used in databases without additional data items. CCCIDM therefore proposed a self-management item set (SMIS), which may be useful for disease management by diabetic patients themselves based on the CIS developed by a working group sponsored by the Japanese Cabinet Secretariat and chaired by Professor Emeritus Naoko Tajima of Jikei University School of Medicine, who was also the first chairperson of the CCCIDM. Two other members of the CCCIDM also participated in the working group. The SMIS for diabetes was approved by the working group in 2012 and was subsequently approved by CCCIDM.

Because patients with diabetes often have other chronic diseases, it can be useful to combine data about diabetes mellitus with data about other chronic diseases. Therefore, in addition to diabetes mellitus, CCCIDM selected hypertension, dyslipidemia, and CKD for consideration because (i) they are associated with high rates of morbidity, (ii) they are associated with considerable personal and socioeconomic burdens, (iii) they are preventable through patient self-management, and (iv) they can be evaluated and monitored using clear clinical parameters, such as blood testing and lifestyle monitoring. After selecting these diseases, CCCIDM invited the Japanese academic associations for each disease (JSH, JAS, and JSN) to form a collaborative extended committee (CEC) to establish consistent overlapping data item sets for all four diseases with the support of the Japanese Cabinet Secretariat. The SMISs for hypertension, dyslipidemia, and CKD were established in combination with the CISs in 2014 and were subsequently published on JAMI's website[3]. The CIS and SMIS for each disease were standardized in terms of data item name, granularity, and expression or unit used.

In 2015, the JSLM was included in the CEC. Since 2016, the CEC has collaborated with a PHR project entitled 'Research on standardization and establishment of a business model for preventing the aggravation of lifestyle-related diseases, in cooperation with medical insurers, disease management companies, and medical institutions,' administered by the Medical Information System Development Center (MEDIS-DC) and sponsored by the Japan Agency for Medical Research and Development (AMED). The aim of that project was to develop SMISs for implementation in PHR applications by mapping them to version 10 of the Japan Laboratory Analysis Codes (JLAC10)[4]. These codes are the Japanese standard for laboratory testing and can be mapped to logical observation identifier names and codes, which are international common terms (a set of identifiers, names, and codes) for identifying health measurements, observations, and documents[5]. The CEC subsequently determined the boundary values and thresholds for risk stratification, as well as values that could be used to provide smartphone alerts to various users, including patients, family members, and medical staff, based on standard clinical guidelines for the chronic diseases. The CEC also identified parameters that could be used to avoid data input errors and to prompt users to input data into the PHR within the appropriate time interval for each item.

RESULTS

Between 2011 and 2014, the CEC established CISs and SMISs that included the CISs for each of the four chronic diseases and revised them in 2018 (Figures 1 and 2). The CISs comprised 14 items for diabetes mellitus, 13 for hypertension, 13 for dyslipidemia, and 12 for CKD. By eliminating overlapping items, the overall number of CIS items was reduced from 52 to 23 (Figure 2). The SMISs comprised 22 items for diabetes mellitus, 18 for hypertension, 15 for dyslipidemia, and 23 for CKD. After eliminating overlapping items, the total number of SMIS items was reduced from 78 to 41 (Figure 2).

The four CISs and four SMISs were approved by the administrative boards of all six associations in 2015 (the first edition) and in 2018 (the second edition). During 2016 and in August 2018, the CEC developed detailed specifications (Tables S1 to S6) for implementing the four SMISs in PHR applications, described as 'recommended configurations for the PHRs of

chronic diseases.' This was performed in collaboration with a PHR project by MEDIS-DC.

Because the standard clinical guidelines ask stricter indicators for patients with chronic diseases than for healthy people, the CEC determined a basic configuration for healthy people (Table S1) and associated configurations for diabetes mellitus (Table S2), hypertension (Table S3), dyslipidemia (Table S4), CKD (Table S5), and coronary heart disease (Table S6), which were added during a discussion by the CEC for risk assessment of the four chronic diseases. The tables show the various strict values for reminders, alerts, or thresholds for risk stratifications. PHR applications should use the basic configuration (Table S1) to detect possibility of pre-diseases (yellow) or the onset of diseases (orange and red) when the user does not have any previously diagnosed disease. And the additional configuration for the appropriate chronic disease to know the risk of serious complications of the diseases (green; minimum risk, yellow; light risk, orange; moderate risk, red; high risk) when the patient experiences the onset of the disease (Table S2 to S6). If the PHR has various configurations because the patient suffers from more than one of the chronic diseases, the strictest configuration should be used.

The CEC defined fasting and non-fasting conditions for the configuration of PHRs for chronic diseases. The fasting condition follows fasting for 10 h (although the consumption of water and non-calorie tea are acceptable). The values for alerts and risk stratification in the configuration of the PHR refer to fasting condition results for the tests for blood glucose (SMIS-ID 10 in Figure 2), triglycerides (SMIS-ID 18), urine glucose (SMIS-ID 28), and self-monitored blood glucose (no ID). The CEC recommends that PHR applications include a function to identify whether these four items have been measured under the fasting condition.

The SMIS and recommended PHR configuration have several lipid-related indicators, including levels of low-density lipoprotein (LDL) cholesterol (by direct assay), total cholesterol, high-density lipoprotein (HDL) cholesterol, and triglycerides. Additional indicators, such as LDL cholesterol by the Friedewald formula and non-HDL cholesterol, can be calculated from data in the SMIS. However, serum triglyceride levels are affected by eating, and some indicators are unstable in blood samples with high triglyceride levels. Thus, the JAS Guidelines for Prevention of Atherosclerotic Cardiovascular Diseases 2017[6] has specified the following according to triglyceride levels: when

ID of CIS	Item	Unit, expression	CIS of diabetes mellitus	CIS of hypertension	CIS of Dyslipidemia	CIS of CKD
1	Height	cm				
2	Weight	kg				
3	Systolic Blood Pressure	mmHg				
4	Diastolic Blood Pressure	mmHg				
5	LDL Cholesterol	mg/dL				
6	HDL Cholesterol	mg/dL				
7	Smoking	Yes, No, Yes in the past				
8	Serum Creatinine	mg/dL				
9	Urine Protein	–, ±, +, 2 + v, 3 + or over				
10	Blood Glucose	mg/dL				
11	Age diagnosed as Diabetes Mellitus	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, Not yet, Unknown				
12	HbA1c※1	%				
13	ALT	IU/L				
14	Diabetic Retinopathy	Yes, No, Unknown				
15	Age diagnosed as Hypertension	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, Not yet, Unknown				
16	Serum Potassium	mEq/L				
17	Abnormality on ECG	Yes, No, Unknown				
18	Triglyceride	mg/dL				
19	Age diagnosed as Dyslipidemia	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, Not yet, Unknown				
20	Past History of Coronary Diseases	Yes (by contrast study), Yes (by another study), No Unknown,				
21	Age diagnosed as CKD	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, Not yet, Unknown				
22	Serum Albumin	g/dL				
23	Hematuria	–, ±, +, 2 +, 3 + or over (Micro hematuria) , Macro hematuria				

Figure 1 | Core item sets for diabetes mellitus, hypertension, dyslipidemia, and chronic kidney disease[3].

ID of SMIS	Item	Unit, expression	SMIS for Diabetes Mellitus			SMIS for Hypertension			SMIS for Dyslipidemia			SMIS for CKD		
			from Medical	from health chekcup	from home	from Medical	from health check- up	from home	from Medical	from health check- up	from home	from Medical	from health check- up	from home
1	Height	cm	○	○		○	○		○	○		○	○	
2	Weight	kg	○	○		○	○		○	○		○	○	
3	Systolic Blood Pressure	mmHg	○	○		○	○		○	○		○	○	
4	Diastolic Blood Pressure	mmHg	○	○		○	○		○	○		○	○	
5	LDL Cholesterol	mg/dL	○	○		○	○		○	○		○	○	
6	HDL Cholesterol	mg/dL	○	○		○	○		○	○		○	○	
7	Smoking	Yes, No, Yes in the past	○	○		○	○		○	○		○	○	
8	Serum Creatinine	mg/dL	○			○			○			○		
9	Urine Protein	–, ±, +, 2 +, 3 + or over	○	○		○	○		○	○		○	○	
10	Blood Glucose	mg/dL	○	○		○	○		○	○				
11	Age diagnosed as Diabetes Mellitus	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, Not yet, Unknown	○											
12	HbA1c	%	○	○								○	○	
13	ALT	IU/L	○	○					○	○				
14	Diabetic Retinopathy	Yes, No, Unknown	○											
15	Age diagnosed as Hypertension	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, No, Unknown				○								
16	Serum Potassium	mEq/L				○						○		
17	Abnormality on ECG	Yes, No, Unknown				○								
18	Triglyceride	mg/dL	○	○		○	○		○	○		○	○	
19	Age diagnosed as Dyslipidemia	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, No, Unknown							○					
20	Past History of Coronary Diseases	Yes (by contrast study), Yes (by another study), No, Unknown							○					
21	Age diagnosed as CKD	under 10y.o, 10's, 20's, , , 70's, 80y.o. or over, No, Unknown										○		
22	Serum Albumin	g/dL										○	○	
23	Hematuria	–, ±, +, 2 +, 3 + or over (Micro hematuria) , Macro hematuria										○	○	
24	Total Cholesterol	mg/dL	○			○			○			○		
25	Urine Albumin/Creatinine	mg/gCre	○											
26	AST	IU/L	○	○										
27	Waist	cm		○			○			○				
28	Urine Glucose	–, ±, +, 2 + or over	○	○										
29	γ GTP	IU/L	○	○										
30	Diabetic neuropathy	Yes, No, Unknown	○											
31	Regular visit at Dental Clinic (*1)	Yes, No, Unknown	○											
32	Uric Acid	mg/dL				○						○	○	
33	Systolic Blood Pressure at home	mmHg						○						
34	Diastolic Blood Pressure at home	mmHg						○						
35	Family History of Renal Failure(*2)	Yes, No, Unknown										○		
36	Urine Protein /Creatinine	g/gCre										○	○	
37	Urine Protein / Day	g/day										○	○	
38	Serum Total Protein	g/dL										○	○	
39	BUN	mg/dL										○		
40	Hemoglobin	g/dL										○	○	
41	Cystatin C	mg/L										○		

CIS for Diabetes Mellitus | CIS for Hypertension | CIS for Dyslipidemia | CIS for CKD

Figure 2 | The self-management item sets[3].
Notes: (*1) Regular visits to a dental clinic (at least once per year). (*2) A family history of renal failure, including hemodialysis, renal transplantation, or renal failure in a family member of ≤2 degrees of separation

the triglyceride level is <400 mg/dL, LDL cholesterol by the Friedewald formula (only in the fasting condition) or direct assay, or non-HDL-cholesterol, should be used for the evaluation; when the triglyceride level is in the range 400–600 mg/dL, LDL cholesterol (by direct assay but not by the Friedewald formula) or non-HDL-cholesterol should be used for the evaluation; for triglyceride levels in the range 600–1,000 mg/dL, LDL cholesterol by direct assay, but not by the Friedewald formula, should be used for the evaluation; and when triglycerides ≥1,000 mg/dL, triglyceride should be improved before the evaluation of lipid-related indicators.

The JSLM subsequently mapped the SMISs to the JLAC10 (Table 1), and this map was approved by the CEC in 2018. Mapping the SMISs to JLAC10 is complicated because it depends on factors, such as the assay methods and reagents used. Therefore, when PHR providers install actual JLAC10 codes in the system, they should be careful and ensure they use the correct codes.

DISCUSSION

'Big data' has evolved to incorporate clinical information, and it is expected that a vast amount of diabetes-related data will be generated. It is therefore important to develop and implement standardized data item sets for diabetes-related databases. Linking those databases to databases for other chronic diseases should help generate useful, high-quality data. However, attempts to standardize data item sets have often failed because of an excessive number of items. In our approach, we defined the CIS for each disease and then developed SMISs based on those CISs to minimize the number of items.

Our SMISs have been used in databases for three large disease registry studies (Table 2). For example, the Japan Diabetes Comprehensive Database Project Based on an Advanced Electronic Medical Record System (J-DREAMS), administered by the National Center for Global Health and Medicine and the JDS, used all of our SMIS items for diabetes mellitus[7,8]. In

Table 1 | Mapping similarities between the self-management item set and the Japan Laboratory Analysis Code version 10 (JLAC10)

Number	Item name	Expression/unit	JLAC10 code	Supplement
1	Hight	cm	9N001000000000001	
2	Weight	kg	9N006000000000001	
3	Systolic blood pressure	mmHg	9A751000000000001	
4	Diastolic blood pressure	mmHg	9A761000000000001	
5	LDL-cholesterol	mg/dL	3F077000002327101	
			3F077000002391901	Friedewald
6	HDL cholesterol	mg/dL	3F070000002327101	
7	Smoking	Yes, No, Yes in the past	9N736000000000011	
8	Serum creatinin	mg/dL	3C015000002327101	
9	Urine protein	-, ±,+, 2+, 3+or over	1A990000000190153	Urinary test strip method
10	Blood glucose	mg/dL	3D010****01927201	NaF,Plasma
			**** [1,288: before breakfast, 1,289: after breakfast, 1,290: before lunch, 1,291: after lunch, 1,292: before supper, 1,293: after supper, 1,299: casual, 1,300: fasting]	
11	Age diagnosed as diabetes mellitus	Less than 10y.o, 10s, 20s, 70s, 80 y.o or over, Unknown	9N041000000000011	
12	HbA1c (NGSP)	%	3D046000001920402	
13	ALT	IU/L	3B045000002327201	
14	Diabetic retinopathy	Yes, No, Unknow	9N042000000000011	
15	Age diagnosed as hypertension	Less than 10y.o, 10s, 20s, 70s, 80 y.o or over, Unknown	9N043000000000011	
16	Serum potacium	mEq/L	3H015000002326101	
17	Abnormality on ECG	Yes, No, Unknow	9A110160700000011	
18	Trigriceride	mg/dL	3F0150****2327101	
			**** [1,288: before breakfast, 1,289: after breakfast, 1,290: before lunch, 1,291: after lunch, 1,292: before supper, 1,293: after supper, 1,299: casual, 1,300: fasting]	
19	Age diagnosed as dyslipidemia	Less than 10y.o, 10s, 20s, 70s, 80 y.o or over, Unknown	9N044000000000011	
20	Past history of coronary diseases	Yes (by contrast study), Yes (by another study), No, Unknown	9N721000000000011	
21	Age diagnosed as CKD	Less than 10y.o, 10s, 20s, 70s, 80 y.o or over, Unknown	9N045000000000011	
22	Serum albumin	g/dL	3A015000002327101	
23	Hematuria	-, ±,+, 2+, 3+or over (Micro hematuria), Macrohematuria	1A990000000190159	Urinary test strip method
24	Total cholesterol	mg/dL	3F050000002327101	
	Non-HDL-cholesterol	mg/dL	3F069000002391901	
25	Urine albumin/Creatinin	mg/gCr	3A015000000106128	
26	AST	IU/L	3B035000002327201	
27	Waist	cm	9N016160100000001	
28	Urine glucose	-, ±,+, 2+or over	1A990****00190154	Urinary test strip method
			1A020****00190111	Specific health check-up code

Table 1 (*Continued*)

Number	Item name	Expression/unit	JLAC10 code	Supplement
			**** [,1288: before breakfast, 1,289: after breakfast, 1,290: before lunch, 1,291: after lunch, 1,292: before supper, 1,293: after supper, 1,299: casual, 1,300: fasting]	
29	γ-GTP	IU/L	3B090000002327101	
30	Diabeteic neuropathy	Yes, No, Unknown	9N046000000000011	
31	Regular visit at dental clinic	Yes, No, Unknown	9N531000000000011	
32	Uric acid	mg/dL	3C020000002327101	
33	Systolic blood pressure at home	mmHg	9A751000000099501	
34	Diastolic blood pressure at home	mmHg	9A761000000099501	
35	Family history of renal failure	Yes, No, Unknown	9N047000000000011	
36	Urine protein/Creatinin	g/gCr	1A015000000127128	
37	Urine protein/Day	g/day	1A015000000427126	
38	Serum total protein	g/dL	3A010000002327101	
39	BUN	mg/dL	3C025000002327201	
40	Hemoglobin	g/dL	2A990000001930953	
			2A030000001930901	Specific health check-up code
41	Cystatin C	mg/L	3C016000002306201	
Extra Items	Weight at home	kg	9N006000000099401	
Extra Items	Self-monitoring blood glucose	mg/dL	3D010****01899101	
			**** [1,288:before breakfast, 1,289: after breakfast, 1,290: before lunch, 1,291: after lunch, 1,292: before supper, 1,293: after supper, 1,299: casual, 1,300: fasting]	

Table 2 | Outline timetable of implementation using the self-management item set (SMIS) and the recommended configuration for personal health records (PHRs)

	Startup	Diabetes SMIS	Hypertension SMIS	Dyslipidemia SMIS	CKD SMIS	Specification for PHR
Case Registration cohort						
J-DREAMS	2015~	◎	–	–	–	–
J-CKD-DB	2015~	–	–	–	○	–
J-DOME	2016~	◎	◎	◎	◎	–
PHR project						
PHR (by MEDIS-DC)	2016~	◎	◎	◎	◎	◎
PHR (DialBetics)	2018~?	○ (planned)	–	–	○ (planned)	○ (planned)

◎: full implementation, ○: partial implementation.

addition, J-CDK-DB[9], administered by the JSN, used some of the CKD SMIS items, which can be automatically output from the SS-MIX2 system[10], and the Japan Medical Association Diabetes Database of Clinical Medicine (J-DOME), administered by the Japan Medical Association to collect clinical information about diabetes, used all of our SMIS items for all four chronic diseases[11].

We implemented all the SMIS items for the four chronic diseases with detailed specifications for their inclusion in a PHR application that is being developed as part of the MEDIS-DC

project, funded by AMED. We are also conducting verification studies in the cities of Nishinomiya (Hyogo Prefecture), Taku (Saga Prefecture), and Koriyama (Fukushima Prefecture). Finally, another PHR project, 'Expanding and strengthening cooperation of a CKD database and establishment of a comprehensive database,' initiated in 2017 and also funded by AMED, is using our diabetes-related SMIS items in the 'DialBetics' PHR application[12].

CONCLUSIONS

In conclusion, CCCIDM and the CEC established standardized CISs and SMISs for the four chronic diseases. They also developed specifications for implementing these items in PHR applications, such as identifying values for risk stratification, generating alerts using information and communications technology systems, avoiding data input errors, and generating reminders to input the SIMS data. In addition, a table was developed to map the item sets to the JLAC10 codes.

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DISCLOSURE

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COMPLIANCE WITH ETHICAL STANDARDS

There are no ethical issues associated with this report.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

Table S1 | Recommended configuration for personal health records based on the self-management item set for healthy people (the basic configuration).
Table S2 | Recommended configuration for personal health records based on the self-management item set for patients with diabetes mellitus (the diabetic configuration).
Table S3 | Recommended configuration for personal health records based on the self-management item set for patients with hypertension (the hypertension configuration).
Table S4 | Recommended configuration for personal health records based on the self-management item set for patients with dyslipidemia (the dyslipidemia configuration).
Table S5 | Recommended configuration for personal health records based on the self-management item set for patients with chronic kidney disease (the CKD configuration).
Table S6 | Recommended configuration for personal health records based on the self-management item set for patients with coronary heart disease (the coronary heart disease configuration).