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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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
Core item sets, Lifestyle related diseases, Personal health record

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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.

The following authors are members of Japan Association for Medical Informatics: Naoki Nakashima, Makoto Ohara, Akira Gochi, Yasushi Matsumura, Michio Kimura, Kazuhiro Ohe. The following authors are members of Japan Diabetes Society: Mitsuhiko Noda, Kohjiro Ueki, Tatsuhiko Koga, Michio Hayashi, Katsuya Yamazaki, Tomoko Nakagami, Yukio Tanizawa.
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The article is a report from the Collaborative Committee of Clinical Informatization in Diabetes Mellitus (by the Japan Diabetes Society and the Japan Association for Medical Informatics) with the Collaborative Initiative by additional four Japanese clinical associations (the Japanese Society of Laboratory Medicine, the Japanese Society of Hypertension, the Japanese Society of Nephrology and the Japan Atherosclerosis Society). The article has been jointly published in Journal of Diabetes Investigation (the official journal of the Asian Association for the Study of Diabetes) and Diabetology International (the official English journal of the Japan Diabetes Society: https://doi.org/10.1007/s13340-019-00389-7) by the Japan Diabetes Society.
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BACKGROUND AND AIMS

Many databases have been developed to store and generate information about diabetes mellitus and other chronic diseases1,2, 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 website3. 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 Japanese Laboratory Analysis Codes (JLAC)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 documents5. 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..."
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 has specified the following according to triglyceride levels: when

| Item                                      | Unit, expression | CIS of diabetes mellitus | CIS of hypertension | CIS of Dyslipidemia | CIS of CKD |
|-------------------------------------------|------------------|--------------------------|---------------------|---------------------|------------|
| Height                                    | cm               |                          |                     |                     |            |
| Weight                                    | kg               |                          |                     |                     |            |
| Systolic Blood Pressure                   | mmHg             |                          |                     |                     |            |
| Diastolic Blood Pressure                  | mmHg             |                          |                     |                     |            |
| LDL Cholesterol                          | mg/dL            |                          |                     |                     |            |
| HDL Cholesterol                          | mg/dL            |                          |                     |                     |            |
| Smoking                                   | Yes, No, Yes in the past |
| Serum Creatinine                          | mg/dL            |                          |                     |                     |            |
| Urine Protein                             | –, +, 2 +, 3 + or over |
| Blood Glucose                             | mg/dL            |                          |                     |                     |            |
| Age diagnosed as Diabetes Mellitus        | under 10y.o, 10’s, 20’s, 30’s, 60y.o. or over, Not yet, Unknown |
| HbA1c                                     | %                |                          |                     |                     |            |
| ALT                                       | U/L              |                          |                     |                     |            |
| Diabetic Retinopathy                      | Yes, No, Unknown |                          |                     |                     |            |
| Age diagnosed as Hypertension             | under 10y.o, 10’s, 20’s, 30’s, 60y.o. or over, Not yet, Unknown |
| Serum Potassium                           | mg/dL            |                          |                     |                     |            |
| Abnormality on ECG                        | Yes, No, Unknown |                          |                     |                     |            |
| Triglyceride                              | mg/dL            |                          |                     |                     |            |
| Age diagnosed as Dyslipidemia             | under 10y.o, 10’s, 20’s, 30’s, 60y.o. or over, Not yet, Unknown |
| Past History of Coronary Diseases         | Yes (by contrast study), Yes (by another study), No, Unknown |
| Age diagnosed as CKD                      | under 10y.o, 10’s, 20’s, 30’s, 60y.o. or over, Not yet, Unknown |
| Serum Albumin                             | g/dL             |                          |                     |                     |            |
| Hematuria                                 | –, +, 2 +, 3 + or over (Micro hematuria, Macro hematuria) |
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.

**Figure 2** The self-management item sets.3
Notes: (*) 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

**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
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      | Height    | cm              | 9N00100000000001 |            |
| 2      | Weight    | kg              | 9N00600000000001 |            |
| 3      | Systolic blood pressure | mmHg        | 9A75100000000001 |            |
| 4      | Diastolic blood pressure | mmHg      | 9A76100000000001 |            |
| 5      | LDL-cholesterol | mg/dL     | 3F07700000232710 |            |
| 6      | HDL cholesterol | mg/dL      | 3F07000000232710 | Friedewald |
| 7      | Smoking   | Yes, No, Yes in the past | 9N73600000000001 |            |
| 8      | Serum creatinin | mg/dL     | 3C01500000232710 |            |
| 9      | Urine protein | –, ±+, 2+, 3+or over | 1A990000000190153 | Urinary test strip method |
| 10     | Blood glucose | mg/dL        | 3D01000000192720 | NaF, Plasma |
| 11     | Age diagnosed as diabetes mellitus | Less than 10y.o, 10s, 20s, 70s, 80 y.o or over, Unknown | 9N04100000000001 |            |
| 12     | HbA1c (NGSP) | %             | 3D04600000192040 |            |
| 13     | ALT       | IU/L           | 3B04500000232720 |            |
| 14     | Diabetic retinopathy | Yes, No, Unknown | 9N04200000000001 |            |
| 15     | Age diagnosed as hypertension | Less than 10y.o, 10s, 20s, 70s, 80 y.o or over, Unknown | 9N04300000000001 |            |
| 16     | Serum potacium | mEq/L       | 3H01500000232610 |            |
| 17     | Abnormality on ECG | Yes, No, Unknown | 9A11016070000001 |            |
| 18     | Trigliceride | mg/dL         | 3F01500000232710 |            |
| 19     | Age diagnosed as dyslipidemia | Less than 10y.o, 10s, 20s, 70s, 80 y.o or over, Unknown | 9N04400000000001 |            |
| 20     | Past history of coronary diseases | Yes (by contrast study), Yes (by another study), No, Unknown | 9N72100000000001 |            |
| 21     | Age diagnosed as CKD | Less than 10y.o, 10s, 20s, 70s, 80 y.o or over, Unknown | 9N04500000000001 |            |
| 22     | Serum albumin | g/dL         | 3A01500000232710 |            |
| 23     | Hematuria | –, ±+, 2+, 3+or over (Micro hematuria, Macrohematuria) | 1A990000000190159 | Urinary test strip method |
| 24     | Total cholesterol | mg/dL       | 3F05000000232710 |            |
| 25     | Non-HDL-cholesterol | mg/dL | 3F06900000239190 |            |
| 26     | Urine albumin/Creatinin | mg/gCr | 3A015000000106128 |            |
| 27     | AST       | IU/L           | 3B03500000232720 |            |
| 28     | Waist     | cm             | 9N01616010000001 |            |
| 29     | Urine glucose | –, ±+, 2+or over | 1A990000000190154 | Urinary test strip method |

SPECIAL REPORT
Nakashima et al.

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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

**Table 1** (Continued)

| Number | Item name                          | Expression/unit | JLAC10 code | Supplement |
|--------|------------------------------------|-----------------|-------------|------------|
| 29     | \( \gamma \)-GTP                   | IU/L            | 3B0900000002327101 | **** [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] |
| 30     | Diabetic 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            | 9A751000000000050 |            |
| 34     | Diastolic blood pressure at home    | mmHg            | 9A761000000000050 |            |
| 35     | Family history of renal failure     | Yes, No, Unknown| 9N047000000000011 |            |
| 36     | Urine protein/Creatinin            | g/gCr           | 1A015000000127102 |             |
| 37     | Urine protein/Day                  | g/day           | 1A015000000427102 |             |
| 38     | Serum total protein                | g/dL            | 3A010000002327101 |             |
| 39     | BUN                                | mg/dL           | 3C025000002327201 |             |
| 40     | Hemoglobin                         | g/dL            | 2A9900000001930953 | Specific health check-up code |
| 41     | Cystatin C                         | mg/L            | 3C016000000306201 |             |
| Extra Items | Weight at home                  | kg              | 9N006000000009401 |             |
| Extra Items | Self-monitoring blood glucose     | mg/dL           | 3D010000001899101 |             |

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

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

@: full implementation, O: partial implementation.

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In conclusion, CCCIDM and the CEC established standardized CIs and SMIs 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 communication 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).