Design of and rationale for the Japan Diabetes compREhensive database project based on an Advanced electronic Medical record System (J-DREAMS)

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Abstract The “Japan Diabetes compREhensive database project based on an Advanced electronic Medical record System” is a registry of patients with diabetes in Japan. The characteristics of this registry include a clinical information input process using the template function of an electronic medical record (EMR) system [the standard diabetes management template (SDMT)], a standardized exchangeable information storage format [the Standardized Structured Medical Information eXchange 2 (SS-MIX2)], and a secure and efficient information extraction process

[Multipurpose Clinical Data Repository System (MCDRS)]. Together, these characteristics enable efficient data input during routine patient consultations, efficient and exact data extraction from each facility, and the integration of data across different facilities even though these data were generated by EMR systems from different vendors. The SDMT collects clinical information including the type of diabetes, body height and weight, blood pressure, lifestyle, and comorbidities. Completing this template triggers the automatic collection of other information such as fundamental information (sex, year and month of birth, and facility), prescription information, and laboratory examination results. As the information from every routine consultation is saved

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with an anonymized patient ID, linked data can be used as panel data allowing longitudinal investigations. The data obtained from the registry will allow analyses, for example, mortality and morbidity risk, by various characteristics or drug types and may reveal unmet needs that inform future diabetes care.

Keywords Diabetes · Registry · Japan · Medical informatics · Electronic medical record · SS-MIX2

Introduction

With the increase in average life expectancy in Japan, it has become critically important to improve long-term outcomes for patients with diabetes who are at high risk for renal disorders that can lead to dialysis, coronary artery disease (CAD), stroke, and cancer. In Japan, diabetes accounts for as much as 37.6% of renal diseases that result in dialysis [1]; it is also associated with an approximately two- to threefold higher risk of CAD and stroke [2], and it increases the risk of cancer modestly but significantly [3]. Patients with diabetes account for more than 10% of the adult population in Japan [4], posing a serious medical and socioeconomic challenge to society. Reliable epidemiological or registry data of current diabetes care are therefore essential for the appropriate development of treatment guidelines and healthcare policies for addressing the burden of diabetes.

However, there are only limited epidemiological data sources about Japanese patients with diabetes. In contrast to the situation in Denmark and Sweden, which already have national diabetes registries, Japan has never maintained a comprehensive or representative diabetes registry. Japan has a much larger population than those countries, and its health insurance system is more complex [5]. Unlike patients with cancer or cardiovascular disease, who may be captured through an event-driven register with a relatively short follow-up period, patients with diabetes need to be followed up over a longer duration for their data to have sufficient power for identifying possible risks or factors that prevent complications.

Despite these difficult circumstances, there have been notable efforts to collate epidemiological findings about patients with diabetes in Japan. For example, the Japan Diabetes Complications Study, originally an intervention study about lifestyle changes related to type 2 diabetes [6], has provided much epidemiological evidence about diabetes patients in Japan [2, 7, 8]. The Japan Diabetes Clinical Data Management Study Group collected clinical information of diabetes patients, mainly those in the care of board-certified diabetologists [9–11]. The Japan Diabetes Complication and its Prevention prospective study conducted by the Japan Diabetes Society (JDS) have investigated diabetes complications. Although these projects have made considerable

contributions, it was desirable to have a larger and more representative registry of patients with diabetes in Japan to capture information about them with greater validity and precision.

Recently, with the widespread use of electronic medical records (EMRs), healthcare and nursing data are becoming increasingly computerized in the clinical setting. However, because there has never been a de facto standard platform for data entry, the various sets of computerized data are difficult to combine for aggregated analyses. There is an increasing need to establish a research platform that efficiently accumulates and concentrates data from a large number of clinical cases from both specialized care institutions and the numerous general medical facilities; this would allow a database that is representative of the entire population and available to be shared by investigators for research purposes.

In 2007, new standardized storage specifications of EMR data were proposed with the Standardized Structured Medical record Information eXchange (SS-MIX), funded by a Japan Health and Labour Science Research Grant [12]. In 2012, it advanced to its second edition (SS-MIX2) [13], and in 2016, it was designated as one of the Ministry of Health, Labour and Welfare's standards in the field of healthcare information. The SS-MIX2 specifications are expected to become the standard for the accumulation and management of EMR data. In particular, this should enhance the portability of medical information that previously differed in data format from one vendor to another. The SS-MIX2 specifications adopted the considerable progress made in healthcare information standards in Japan, including code standardization regarding laboratory data items and prescription data. A data extraction and registration system, the Multipurpose Clinical Data Registry System (MCDRS), has been developed through the Funding Program for World-Leading Innovative R&D on Science and Technology and the Center of Innovation program; this system allows the efficient collection of clinical data, especially via the SS-MIX2 format.

This progress in medical informatics has allowed us now to develop a large-scale multicenter registry of patients with diabetes, the “Japan Diabetes comprehensive database project based on an Advanced electronic Medical record System” (J-DREAMS). The objective of this report is to describe the establishment of this clinical database, its design, and the rationale behind it.

Methods

The J-DREAMS project

J-DREAMS has been designed as a multicenter, real-world registry study of patients with diabetes. It was initiated in

December 2015 and is under the direction of the National Center for Global Health and Medicine (NCGM).

Study setting and participants

As of March 2017, 35 facilities have participated in the J-DREAMS project, all of which were hospitals designated as educational facilities designated by the JDS (Table 1). The JDS conducted a survey of its member facilities (educational facilities designated by the JDS) regarding the number of patients with diabetes at each facility and the state of healthcare computerization, and NCGM then invited some of the facilities based on the survey results.

This process was needed to ensure the smooth implementation and maintenance of the systems essential for J-DREAMS; the facilities participating in J-DREAMS needed to have EMR systems that incorporated SS-MIX2 storage and a template-based structured-data entry function that could transfer the entered data to the SS-MIX2 storage. To achieve a registry of diabetes patients that provides a substantial sample size for future studies, we plan to increase the number of participating facilities to 100 over the coming 5 years.

The registry includes all patients with diabetes (both out- and inpatients) who attended the diabetes care departments in the facilities participating in J-DREAMS

Table 1 Facilities participating in J-DREAMS as of March 2017

Hospital name	Location of hospital
Asahikawa Medical University Hospital	Asahikawa-shi, Hokkaido
Asahikawa City Hospital	Asahikawa-shi, Hokkaido
NTT East Sapporo Hospital	Sapporo-shi, Hokkaido
Iwate Medical University Hospital	Morioka-shi, Iwate
Akita University Hospital	Akita-shi, Akita
Tohoku University Hospital	Sendai-shi, Miyagi
Jichi Medical University Hospital	Shimotsuke-gun, Tochigi
Jichi Medical University Saitama Medical Center	Saitama-shi, Saitama
University of Tsukuba Hospital	Tsukuba-shi, Ibaragi
The University of Tokyo Hospital	Bunkyo-ku, Tokyo
Juntendo University Hospital	Bunkyo-ku, Tokyo
Medical Hospital, Tokyo Medical and Dental University	Bunkyo-ku, Tokyo
Center Hospital, National Center for Global Health and Medicine	Shinjuku-ku, Tokyo
Kohnodai Hospital, National Center for Global Health and Medicine	Ichikawa-shi, Chiba
Toranomon Hospital	Minato-ku, Tokyo
Kitasato University Kitasato Institute Hospital	Minato-ku, Tokyo
Niigata University Medical and Dental Hospital	Niigata-shi, Niigata
Kanazawa University Hospital	Kanazawa-shi, Ishikawa
Keiju Medical Center	Nanao-shi, Ishikawa
Shinshu University Hospital	Matsumoto-shi, Nagano
Mie University Hospital	Tsu-shi, Mie
Shiga University of Medical Science Hospital	Otsu-shi, Shiga
Osaka University Hospital	Suita-shi, Osaka
Kindai University Hospital	Osakasayama-shi, Osaka
Kobe University Hospital	Kobe-shi, Hyogo
Ehime University Hospital	Toon-shi, Ehime
Tokushima University Hospital	Tokushima-shi, Tokushima
Tottori University Hospital	Yonago-shi, Tottori
Okayama University Hospital	Okayama-shi, Okayama
Yamaguchi University Hospital	Ube-shi, Yamaguchi
Kyushu University Hospital	Fukuoka-shi, Fukuoka
Saga University Hospital	Saga-shi, Saga
Nagasaki University Hospital	Nagasaki-shi, Nagasaki
Kumamoto University Hospital	Kumamoto-shi, Kumamoto
Kagoshima University Medical and Dental Hospital	Kagoshima-shi, Kagoshima

初回・定期統合型

初回・定期統合型

記入したデータを院外に送らない場合は右記にチェック: ☐ データを送らない

現在の定期受診: ☐ あり ☐ なし

糖尿病の種類: ☐ 1型 ☐ 2型 ☐ その他の糖尿病 ☐ 妊娠糖尿病 ☐ 不明

糖尿病の診断

西暦: 年 月 日

歳 ☐ 不明

※診断年月日を分かる範囲で全て記入

診断年月日がすべて不明の場合は年齢を記入、どちらとも分からない場合は不明にチェック

糖尿病の診断契機: ☐ 健診・人間ドック ☐ 高血糖に伴う自覚症状出現(口渴、多飲、多尿など)

☐ 他疾患での検査中に指摘 ☐ その他

糖尿病家族歴: ☐ あり ☐ なし ☐ 不明

日本人以外の人種の場合はチェックして下さい:

☐ 日本人以外

20歳時体重: kg

最大体重: kg

最大体重の時の年齢: 歳

体重: kg 身長: cm

腰囲: cm BMI: kg/m²

血圧: mmHg / mmHg

※体重、身長、腰囲、BMI、血圧は記載時に最も近い日のデータを記入

喫煙: ☐ あり ☐ なし ☐ 過去にあり

飲酒頻度: ☐ 毎日 ☐ 週に4-6日 ☐ 週に1-3日 ☐ 月に1-3日 ☐ 数か月に1日/飲まない

糖尿病関連症に関する眼科での検査: ☐ 検査あり ☐ 検査なし ☐ 不明

※網膜症が検査されているか分からない場合は不明にチェック

糖尿病腎症: ☐ 無または1期 ☐ 2期 ☐ 3期 ☐ 4期 ☐ 5期 ☐ 未評価 ☐ 不明

1期: 正常アルブミン尿(30mg/sCr未満)かつGFR 30以上、

2期: 微量アルブミン尿(30-299mg/sCr)かつGFR 30以上、

3期: 顕性アルブミン尿(300mg/sCr以上)あるいは持続性蛋白尿(0.5g/sCr以上)かつGFR 30以上、

4期: 尿蛋白の状態に関わらずGFR 30未満、

5期: 透析療法中

※微量アルブミン尿や蛋白尿などの評価がされていない場合は未評価にチェック

※評価されているが詳細が分からない場合は不明にチェック

糖尿病神経障害: ☐ あり ☐ なし ☐ 未評価 ☐ 不明

※評価されているが詳細が分からない場合は不明にチェック

最近1年間の低血糖: ☐ あり ☐ なし ☐ 不明

過去に重症低血糖(他者の助けを必要とした低血糖・外来受診・入院を含む)の既往

☐ あり ☐ なし ☐ 不明

高血圧の診断: ☐ あり ☐ なし ☐ 不明

脂質異常症の診断: ☐ あり ☐ なし ☐ 不明

(脂質異常症治療薬内服既往、医師に脂質異常症といわれたことがある、LDL-C140mg/dl以上、HDL-C40mg/dl未満、TG150mg/dl(空腹時)以上のいずれか)

※LDL-CはFriedewald式で算出するが、直読法での測定のみであれば直接法で代用

イベント(既往含む)

☐ 冠動脈疾患(無症候性の心筋虚血や冠動脈狭窄も含む) ☐ 心不全

☐ 脳卒中(無症候性やTIA含む) ☐ 末梢動脈疾患 ☐ 下肢切断 ☐ 慢性腰痛

☐ 慢性肝炎 ☐ 肝硬変 ☐ 透析導入(血液透析・腹膜透析) ☐ 腎移植 ☐ 認知症

☐ 骨折 ☐ 内分泌疾患 ☐ 肺臓/肺島移植 ☐ その他

※イベントは既往や複数回発症したものも含め、「全て」記載して下さい

足白癬: ☐ あり ☐ なし ☐ 未評価 ☐ 不明

※評価されていない場合は未評価に、評価されているが有無が分からない場合は不明にチェック

歯科定期受診: ☐ あり ☐ なし ☐ 不明

歯周病: ☐ あり ☐ なし ☐ 未評価 ☐ 不明

※評価されていない場合は未評価に、評価されているが有無が分からない場合は不明にチェック

他院からの薬(当院で処方されているものは、他科であっても記載しないで下さい)

合剤の場合は当てはまる項目すべてにチェックして下さい

☐ 他院からの糖尿病治療薬あり ☐ 他院からの降圧薬あり ☐ 他院からの脂質異常症治療薬あり

☐ 他院からの抗血小板薬あり ☐ 他院からの薬があるが、内容が不明

☐ 糖尿病専門医の申請・更新のための項目入力

自由記載欄(ここに記載した情報は自施設から外には出ません。情報の整理などにお使い下さい)

やめる

確定

Fig. 1 An example of the standard diabetes management template (NEC version). The templates from the different vendors all collect the same set of information

during the case registry period. Patients who declined to participate in J-DREAMS were not registered; after registration, patients could request their information be deleted from the registry.

Patient data registration and data collection

The process of data collection highlights the characteristics of this patient registry. Here, we provide a brief outline of the data collection system.

The physicians in the diabetes and/or endocrinology departments at the facilities participating in J-DREAMS describe their patients' medical information using the Standard Diabetes Management Template (SDMT) installed in the EMR system at each study site. SDMT is based on the template function installed by default in each EMR system and has been constructed to collect the same series of information from the systems of the different information technology companies that sell EMR systems (Fig. 1). Data registration for each patient requires entering his or her medical information via the SDMT. If a patient declines to be registered, the physician checks the "Intramural use only" checkbox in the SDMT, and that patient's data are then exempted from data extraction as a part of the J-DREAMS database.

All data entered for each patient using the SDMT are automatically converted and stored in the SS-MIX2 "extended" storage in a CDISC-ODM-based XML format defined by our study group [14]. The patient's basic information, prescription history, and clinical laboratory data are stored in the SS-MIX2 "Standardized Storage" in an HL-7 (ISO IS27931) format. Data entry (i.e., registration) for each patient using the SDMT triggers a process in which relevant data, such as his or her basic information (sex, year/month of birth, facility name), prescription status, and clinical laboratory data from the last 3 months, are extracted via the SS-MIX2 Gateway Server (SS-MIX2 GW) onto the MCDRS Collection Agent (the "Collection Agent") and then anonymized on the anonymizing server. As described earlier, if the "Intramural use only" checkbox in the SDMT is checked, this prevents that patients' data from being extracted to the Collection Agent.

After temporary storage at the Collection Agent, the extracted data are automatically or manually timed for forwarding to and storing at NCGM's data center via one of the following three methods: (1) via a virtual private network (VPN), (2) on electronic media, such as CD-R or DVD-R discs, which are physically taken to the NCGM, or (3) via an available LAN cable (from the NCGM hospital).

In each case, all data are anonymized/encrypted before forwarding, and care is taken to ensure the protection of personally identifiable information.

Although almost all of the facilities participating in J-DREAMS have adopted these systems, a few facilities do not forward their information via the SS-MIX2 server or the Collection Agent; in these facilities, clinical information is typed directly onto the MCDRS client (a web browser on a laptop PC) and then forwarded with the anonymized patient ID via the secure socket layer to the data center at NCGM. Access to the MCDRS client is restricted to global IP addresses registered beforehand and is managed by a facility ID and password.

Variables

The variables collected through J-DREAMS are listed in Table 2 (the basic information, prescription history, and clinical laboratory data stored in the SS-MIX2 standardized storage) and in Supplementary Fig. 1 (the clinical information collected using the SDMT and stored in the SS-MIX2 extended storage). These variables were selected from the perspective of their clinical importance to diabetes care. Moreover, the variables listed include all the variables in the "Minimum Data Item Set" (MDIS)", [15] determined by the Joint Committee of the JDS and the Japan Association for Medical Informatics to increase the compatibility of the data with those in other patient registries.

If a patient ceases to attend the facility for some reason (such as transfer, drop out, or death), the physician completes the SDMT prepared for such circumstances.

Follow-up

Physicians in the diabetes and/or endocrinology departments at the facilities participating in J-DREAMS are expected to fill in the SDMT each time they see an outpatient and once per inpatient hospitalization. It takes approximately 5–15 min to complete the SDMT the first time. Thereafter, the physicians can electronically replicate the previous filled template to save time, and they only need to update any information that has changed since the previous visit, such as the patient's body weight and blood pressure, and any complications that have arisen. Information collected at each visit is linked by the anonymized patient ID so that the whole database can be used for longitudinal studies.

Quality assurance

Because the system used in J-DREAMS is still new, it needs to be monitored. Central monitoring is performed using the data stored at the data center. Moreover, there is

Table 2 The items collected through J-DREAMS (basic information, prescription history, and clinical laboratory data)**Basic information**

Year/month of birth

Sex

Hospital code

Laboratory data

Blood samples

Blood cell count

Total protein

Aspartate transaminase

Alanine transaminase

Gamma-glutamyl transpeptidase

Creatine kinase

Total cholesterol

High-density lipoprotein cholesterol

Low-density lipoprotein cholesterol

Triglycerides

Blood urea nitrogen

Creatinine

Potassium

Hemoglobin A1c

Glycoalbumin

1,5-Anhydroglucitol

Blood glucose

Cancer antigen 19-9

Brain natriuretic peptide

Cystatin C

Carcinoembryonic antigen

Thyroid-stimulating hormone

Free triiodothyronine

Free thyroxine

Insulin

C-peptide

Anti-glutamic acid decarboxylase antibodies

Anti-islet antigen 2 antibody

Islet cell cytoplasmic antibody

Zinc transporter 8 antibody

Anti-insulin antibody

Hepatitis B surface antibody

Hepatitis C antibody

Urine samples

Qualitative urinary test

Protein

Albumin

Creatinine

C-peptide

Prescription

All of the patient's prescription information obtained from the participating facility

an on-site monitoring process in which data for several patients are extracted directly from the EMRs at a site and compared with the data stored in the data center. Data quality is assessed, and, if necessary, quality improvement action is taken.

Planned future studies

It is proposed that a cross-sectional survey will be conducted on parameters of interest, such as patient numbers, glycemic control status, treatment status, and the prevalence of associated complications, analyzing these parameters by patient category (e.g., by type of diabetes, including type 1, type 2, gestational, or other forms). Moreover, the study will incorporate a longitudinal survey on parameters of interest, such as complication rates and life prognosis, again analyzed by patient category.

Ethical considerations

The institutional review boards in the NCGM and other collaborating facilities approved the study protocol for J-DREAMS (date of the latest revision approval at NCGM: 13 March 2017, approval no. NCGM-G-001702-07). While preparing this manuscript, Ethical Guidelines for Medical and Health Research Involving Human Subjects of 2014 was revised on 28 February 2017 to fully comply with the Amended Act on the Protection of Personal Information, which is set to come into effect as of 30 May 2017. Therefore, the study protocol for J-DREAMS was fully revised and submitted for the institutional review boards accordingly.

Overview of data collected

As of the end of August 2016 [8 months after the initiation of registration in the first hospital (NCGM)], data were collected and sent to NCGM from 29 participating hospitals. The total number of input of templates was 54,063, from 24,781 unique patients. Among them, 12,874 (57.8% among those whose gender information was collected) were male. The number of patients by type of diabetes is as follows: type 1—1908 (9.0%); type 2—17,622 (83.5%); gestational—134 (0.6%); others—1445 (6.8%). We will present the results of cross-sectional analyses in more detail and collecting more patients.

Discussion

In this report, we have described the protocol for J-DREAMS. Through this project, we expect to obtain clinical data that will be used to elicit the epidemiology of

diabetes patients in Japan. J-DREAMS utilizes advanced EMR systems, template-based data collection, and data retrieval systems for laboratory results and prescriptions to create a large-scale diabetes registry with relative ease in terms of both introduction and maintenance. The eventual scope of this registry is expected to include 100 participating facilities covering up to 200,000 patients. Data acquisition and analysis will be facilitated by J-DREAMS in several ways. First, there is close integration between daily patient management using EMRs and registry data entry. Second, laboratory data and prescription information are automatically extracted and stored. Third, the preferred method of data transfer is via a network so that all the standardized registry data will be electronically transferred to the coordinating facility, NCGM, where it will be analyzed. The data extraction systems in J-DREAMS that utilize EMR-embedded templates to collect clinical information are applicable and expandable to other diseases, such as cardiovascular diseases.

Several points noted at the launch of J-DREAMS require improvement if this diabetes registry is to be successful. The 35 initial participating facilities are all large referral centers for diabetes and endocrinology; this means that to represent current diabetes care in Japan, care should be given to the inclusion of future participating facilities. It is estimated that more than half of the patients with diabetes in Japan are cared for by office-based primary care providers [16]; an informatics infrastructure to retrieve data from those patients is planned and will be created separately from J-DREAMS, and it is expected that the core of the data from both registries will be shared [17]. Because office-based diabetology/endocrinology specialists care for a large proportion of the patients with diabetes in Japan, data from those practices must be shared with the data from J-DREAMS for a complete diabetes registry.

Although laboratory data items and prescription data have in general been described according to standardized code systems throughout Japan, we found that multiple local variations in those coding systems were associated with individual EMR systems. Care has been taken to accommodate those local variations and to ensure correct data acquisition by referencing to mapping tables.

Another issue is the facilitation of overall data analysis. It is intended that the systems utilized in J-DREAMS acquire patient data with ease and in a timely fashion. With the preferred data transfer through a network (VPN), the J-DREAMS registry will accumulate a large amount of patient data (in terms of both the number of patients and through multiple time points); this would be unattainable using conventional registries. J-DREAMS registry can also be flexible; data acquired through the registry can be used for cross-sectional as well as longitudinal cohort studies. Computational power and process, data quality management, and

well-planned data assembly are several key areas for timely data summary and ultimately for the success of the J-DREAMS registry.

Personal information security is of critical importance while conducting medical research. The Amended Act on the Protection of Personal Information, which came into effect on 30 May 2017 in Japan, classifies medical history as “special care-required” personal information and thus prohibits acquiring such information without proper consent. Registry studies, like other types of public health research, are only representative with complete enumeration of study subjects, which might be impossible if conventional opt-in consent is required for all the study participants. Ethical Guidelines for Medical and Health Research Involving Human Subjects of 2014 was revised on 28 February 2017 to clarify this issue; proper handling of medical history in the research setting and obtaining appropriate consent, including opt-out consent, are clearly defined. The protocol of J-DREAMS was revised accordingly and submitted for the institutional review boards in participating institutes. Moreover, in the J-DREAMS registry, several steps of anonymization take place and data are analyzed in mass; thus, potential harm to the study subjects even in the case of data leakage is thought to be exceedingly small.

In conclusion, we launched the J-DREAMS registry based on advanced EMR systems. This registry will provide both cross-sectional and longitudinal epidemiological data for patients with diabetes in Japan. J-DREAMS will also be used for fact finding and generating hypotheses about diabetes care in Japan, thus potentially leading to improvements in the quality of care.

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J-DREAMS is a research project driven by NCGM. NCGM and the JDS established a joint committee, within which members discuss the detail of study design and analysis from a scientific perspective.

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Compliance with ethical standards

Conflict of interest Kayo Waki received a clinical research grant from NTT Docomo. The other authors declare that they have no conflict of interest.

Human rights statement and informed consent All procedures followed were in accordance with Ethical Guidelines for Medical and Health Research Involving Human Subjects of 2014 and its revision of 2017 and with the Helsinki Declaration of 1964 and later versions. Based on the ethical guidelines, an opt-out consent method was chosen. By displaying posters in hospitals or through websites, patients were informed of the objectives of the study, and permission for the investigators to collect PMR data was sought. We offered opportunity for the participants to opt out of participation in the registry by filling out the opt-out form.

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