

# Appropriate definition of diabetes using an administrative database: A cross-sectional cohort validation study

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## Keywords

Administrative claims data, Diabetes, Validation

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## ABSTRACT

**Aims/Introduction:** The purpose of the present study was to quantify errors in the diagnosis of diabetes for use in the national database, using a sufficient population size.

**Materials and methods:** A claims database constructed by the JMDC (Tokyo, Japan), using standardized disease classifications and anonymous record linkage, was used in this validation study. We included patients with health insurance claims data from April 2005 to March 2019 in the JMDC claims database. We excluded patients without a record of specific health checkups in Japan. Sample size calculation was based on a 5% prevalence of diabetes and 0.4% absolute accuracy (i.e., 1,250,000 individuals), to calculate the sensitivity, specificity, positive predictive value and negative predictive value.

**Results:** In total, 2,999,152 patients were included in this study, of which 165,515 were classified as having diabetes based on specific health checkups (validation cohort prevalence of 5.5%). The newly devised algorithm had three elements – the diagnosis-related codes for diabetes without suspected flag, the medication codes for diabetes and then these two codes on the same record – and yielded a sensitivity of 74.6%, positive predictive value of 88.4% and Kappa Index of 0.80 (the highest values).

**Conclusions:** In future claims database studies, our validated algorithms will be useful as diagnostic criteria for diabetes.

## INTRODUCTION

The National Database of Health Insurance Claims and Specific Health Checkups of Japan (NDB) is a comprehensive database of health insurance claims data under Japan's National Health Insurance system,<sup>1</sup> and it is one of the largest administrative databases worldwide<sup>2–7</sup>. The NDB includes information on the administrative data of all insured people (approximately 120 million people) in Japan<sup>1</sup>. The NDB also includes information on specific health checkups of 29 million people<sup>8</sup>.

Over the past decade, real-world studies, including administrative claims data, have provided evidence in clinical research<sup>9,10</sup>. Administrative claims databases, such as the

Centers for Medicare and Medicaid Services (CMS) Open Payments Database in the US, Clinical Practice Research Datalink (CPRD) in the UK and NDB Japan, provide information on large samples of patients considered to be representative of the target population; however, their purpose for data collection is administrative rather than for research. Because key clinical variables (e.g., severity), such as medications for which patients pay out-of-pocket, patient-reported outcomes, lifestyle variables and laboratory results, are typically not captured, it is necessary to establish a unique definition of the disease that is different from the clinical definition<sup>11</sup>.

In the claims database, diseases are defined based on the combination of some codes, such as diagnosis-related codes, medicine codes, medical practice codes and specific equipment codes. It is difficult to define diseases based on the codes alone because of the suspected flag to insure medical examination and because of the confirmed diagnosis-related codes that are unsuitable for clinical diagnostic criteria. It is also difficult to

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[Correction added on 1 September 2021, after first online publication: All appearances of the term 'Japan Medical Center' in this article have been amended to 'JMDC' accordingly.]

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validate the definitions, because the NDB is prohibited from being linked with another database.

Diabetes is often defined using diagnosis-related codes and diabetic medications<sup>12</sup>. Although a previous study proposed a definition of diabetes, there was no mention of how to handle data, such as the date of diagnosis, the diagnosis-related codes with the suspected flags, and the diagnosis-related codes and medication codes on the other records. It is important for researchers to use tested algorithms to help further studies refine and utilize appropriate algorithms<sup>13</sup>. We validated additional algorithms, including the handling of information associated with diagnosis-related codes and medication codes. The purpose of the present study was to quantify errors in the diagnosis of diabetes for use in the NDB, using a sufficient population size.

## MATERIALS AND METHODS

The present validation study was approved by the ethics committee of Nara Medical University (1123-6, 8 October 2015). The need for informed consent was waived owing to the retrospective nature of the study. All patient data were anonymized before analysis. The principles outlined in the Declaration of Helsinki were followed. A claims database constructed by the JMDC (JMDC; Tokyo, Japan), using standardized disease classifications and anonymous record linkage<sup>14</sup>, was used in the present validation study. This claims database was constructed with monthly claims from all medical institutions and pharmacies, specific health checkups and registries in Japan submitted from January 2005 to March 2019, which included approximately 7,235,649 insured persons (approximately 5.7% of the Japanese population), comprised mainly of company employees and their family members. The JMDC database provided information on the beneficiaries, including encrypted personal identifiers, age, sex, International Classification of Diseases 10th revision procedure and diagnostic codes, as well as the name, dose and duration (days) with respect to the prescribed and/or dispensed drugs. All drugs were coded according to the Anatomical Therapeutic Chemical classification of the European Pharmaceutical Market Research Association. An encrypted personal identifier was used to link claims data from different hospitals, clinics and pharmacies. A deterministic linkage or probabilistic linkage was not carried out.

We included patients with a record of the health insurance claims data from April 2005 to March 2019 in the JMDC claims database. We excluded patients without a record of specific health checkups in Japan. Sample size calculation was based on a 5% prevalence of diabetes and 0.4% absolute accuracy (i.e., 1,250,000 individuals), to calculate the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV). As aforementioned, the JMDC claims database included more than 1,250,000 individuals required for the sample size calculation.

The candidate population included patients with diabetes identified based on algorithm 1–17 (Table 1). Algorithms 1–12

were separated using a combination of five elements: (i) whether they had diagnosis-related codes for diabetes, which are shown in Table S1; (ii) whether the date of diabetes diagnosis was identified; (iii) whether the diagnosis-related codes had a suspected flag; (iv) whether they had medication codes for diabetes, as shown in Table S2; and (v) whether the diagnosis-related codes and medication codes are on the same record (“receipts” are issued monthly for each patient and each medical institution). Algorithms 1–12 were designed with various combinations of these elements. Algorithms 13, 14 and 15 included measurement of hemoglobin A1c (HbA1c) or glycoalbumin, glucose and urine albumin, respectively. Algorithm 16 included any diagnosis-related code, medication for diabetes and medical action codes as diabetes, as presented in Tables S1–S3, in the view to the highest sensitivity. Algorithm 17 included algorithm 12 and measurements of hemoglobin A1c or glycoalbumin and glucose, in the view to the highest specificity. Because of the much lower number of patients with medical action codes, only HbA1c, glycoalbumin and glucose were used in algorithm 17.

Patients were classified as having or not having diabetes based on: (i) HbA1c ( $\geq 6.5\%$ ) and fasting blood glucose ( $\geq 126$  mg/dL); (2) HbA1c ( $\geq 6.5\%$ ) and a random blood glucose level  $\geq 200$  mg/dL; (iii) the use of antidiabetes drugs documented in the specific health checkups records; (iv) fasting blood glucose  $\geq 126$  mg/dL with diabetic retinopathy; (v) a random blood glucose value  $\geq 200$  mg/dL with diabetic retinopathy; or (vi) fasting blood glucose  $\geq 126$  mg/dL, a random blood glucose value  $\geq 200$  mg/dL or diabetic retinopathy on two occasions (the second occasion indicates the onset of diabetes), according to the Japanese guideline<sup>15</sup>.

Descriptive statistics were used to characterize the study population. We computed the sensitivity, specificity, PPV, NPV, prevalence, kappa value and Youden Index for each algorithm by sex, age class and Japanese academic years (from April to March) with corresponding 95% confidence intervals. Sensitivity and specificity were the probabilities of each algorithm correctly identifying patients with and without diabetes, respectively. PPV was the proportion of those identified by an algorithm as having diabetes who were truly diagnosed with diabetes. NPV was the proportion of those identified by an algorithm as not having diabetes who truly did not have diabetes. The prevalence estimates were calculated for each algorithm. A kappa statistic was calculated for the agreement between each algorithm and the reference standard, in an attempt to identify the algorithms that maximize kappa<sup>16</sup>. The Youden Index was calculated to equally weigh sensitivity and specificity, and it was calculated as follows: (sensitivity + specificity) – 1.

Following the identification of the optimal algorithm, a manual chart review of false positive and false negative cases was carried out to determine the reasons for misclassification. All analyses were carried out using Microsoft SQL Server 2016 Standard<sup>®</sup> (Microsoft Corp., Redmond, WA, USA) and IBM SPSS for Windows (version 25.0; IBM Corp., Armonk, NY, USA).

**Table 1** | Algorithms for diagnosis of diabetes

	Table S1		Table S2		Table S3				
	With diagnosis-related codes of diabetes	With the identified date diagnosed diabetes	Diagnosis-related codes without suspected flag	(d) With medication for diabetes	(e) With diagnosis and medication codes on the same record	(f) Measuring hemoglobin A1c or glycoalbumin	Measuring glucose	Measuring urinal albumin	Others
Algorithm 1	○								
Algorithm 2				○					
Algorithm 3	○			○					
Algorithm 4	○			○	○				
Algorithm 5	○	○							
Algorithm 6	○	○		○	○				
Algorithm 7	○		○						
Algorithm 8	○		○	○					
Algorithm 9	○		○	○	○				
Algorithm 10	○		○	○	○				
Algorithm 11	○	○	○	○					
Algorithm 12	○	○	○	○	○				
Algorithm 13						○			
Algorithm 14							○		
Algorithm 15								○	
Algorithm 16									
Algorithm 17	○	○	○	○	○	○	○	○	

Algorithm 16 is for diagnosis of diabetes, which diagnoses patients who have any diagnosis-related code, medication for diabetes or medical action codes as diabetes.

## RESULTS

### Reference standard

In total, 2,999,152 patients were included in the present study, and 165,515 patients were classified as having diabetes based on specific health checkups (validation cohort prevalence of 5.5%). Table 2 shows the characteristics of the patients in this validation cohort.

### Administrative data algorithm validation

Table 3 shows the accuracy of the administrative data algorithms in identifying patients with diabetes, using the JMDC claims database. The accuracy assessment of both algorithms 9 and 12 showed a sensitivity of 74.6%, PPV of 88.4% and Kappa Index of 0.80, which were the highest values. The algorithms using only diagnosis-related codes (algorithms 1, 5, 7 and 10) resulted in sensitivities of 91.7, 91.7, 88.0 and 88.0%, respectively. Additionally, they resulted in PPVs of 17.7, 17.7, 37.9 and 37.9%. The algorithms including medication codes (algorithms 2, 3, 4, 6, 8, 9, 10, and 12) resulted in sensitivities of 74.8, 74.7, 74.6, 74.7, 74.7, 74.6, 74.7 and 74.6%, respectively, and PPVs of 85.3, 86.0, 87.9, 86.0, 87.4, 88.4, 87.4 and 88.4%. In particular, the algorithm using only medication codes (algorithm 2) resulted in a sensitivity of 74.8%, PPV of 85.3% and Kappa Index of 0.79.

### Supplemental raw data for original validated algorithms

Raw data for making original tested algorithms for diabetes in future administrative claims database studies are shown in Tables S4 and S5. Because Table S5 includes the information of

specific health checkups, reference standards can be changed if necessary.

## DISCUSSION

In the present study, we quantitatively evaluated the sensitivity and specificity of 17 algorithms for the diagnosis of diabetes based on the national claims data, using the JMDC claims database, which provided well-balanced algorithms for diagnosis (algorithms 9 and 12) based on the Kappa Index. These algorithms were in almost perfect agreement with the diagnosis based on blood test values and diabetic prescriptions. Algorithms 9 and 12 had three elements: the diagnosis-related codes for diabetes without suspected flag, the medication codes for diabetes and then these two codes on the same record. We also found that using the diabetes diagnosis date had no effect on the diagnosis of diabetes, as in algorithms 9 and 12.

If the desired result is to generalize to all people with diabetes (generalization), algorithm 16 is useful, with the highest sensitivity of 94.0%. To classify patients as to whether they have diabetes for outcome, algorithm 17 has the highest specificity. To identify cohorts of patients with diabetes, algorithms 9 and 12 have the highest PPV. To reduce the likelihood that people have diabetes, algorithm 1 has the highest NPV. In this manner, we have provided validated algorithms that match the research settings.

Previously, an algorithm for identifying diabetes in Canada was reported<sup>17</sup>. Although it had a sensitivity of 84.2%, specificity of 99.2%, PPV of 92.5% and Kappa Index of 0.87, it is not applicable to Japan because of differences in medical situations, including insurance systems. In the present study, with the use of only the disease name with or without suspected flag, many false positives were observed in the diagnosis (algorithms 1, 5, 7 and 10), suggesting that when diabetes is defined only by disease-related codes, false positives might largely occur. It is easy to speculate that the disease codes were inputted when the examination of HbA1c value needed to be insured.

In contrast, other algorithms using medication codes have well-balanced values of sensitivity, specificity, PPV, NPV, Kappa Index and Youden Index. People with a false negative diagnosis were untreated or might not have required drug therapy. In fact, the age-standardized percentage of treated individuals among those requiring treatment for diabetes was 79.9% (95% confidence interval: 76.7–83.1) during the period 2013–2017.<sup>18</sup> People with a false positive diagnosis might be unaware that they are being prescribed diabetes medication.

The present study had several limitations. First, we used the JMDC claims database and excluded patients without a record of specific health checkups. Thus, there might have been a selection bias. Generalizability is controversial, and further validation studies are required. Second, our algorithm using medication codes overlooked patients with untreated diabetes or those who did not require drug therapy. The National Health and Nutrition Survey in Japan (2020) reported that 65.7% of those who have been diagnosed with diabetes have been

**Table 2** | Characteristics of the patients in the validation cohort

Birth year	Females		Males	
	with DM	Without DM	with DM	Without DM
1930–1934	1	22	1	10
1935–1939	131	1,364	257	1,216
1940–1944	967	8,177	2,072	9,072
1945–1949	2,628	26,418	8,084	40,500
1950–1954	5,089	66,905	22,774	109,782
1955–1959	6,232	103,741	28,013	151,915
1960–1964	5,516	139,813	27,359	199,288
1965–1969	4,260	175,850	21,583	232,632
1970–1974	3,207	206,487	14,524	260,760
1975–1979	1,445	157,285	6,648	218,725
1980–1984	530	93,634	2,256	154,513
1985–1989	284	76,947	996	141,644
1990–1994	152	67,668	381	116,726
1995–1999	39	26,624	84	44,647
2000–2004	1	389	1	883
Total	30,482	1,151,324	135,033	1,682,313

With/without diabetes mellitus (DM) is classified as having or not having diabetes based on the health checkups.

**Table 3** | Accuracy of administrative data algorithms to identify patients with diabetes

Algorithm	TP	TN	FN	FP	Sensitivity (%)	95% CI	Specificity (%)	95% CI	PPV (%)	95% CI	NPV (%)	95% CI	Prevalence estimate	Kappa	Youden
Algorithm 1	151,751	2,127,217	13,764	706,420	91.7%	91.6%	75.1%	75.0%	17.7%	17.6%	17.8%	17.6%	0.29	0.22	0.67
Algorithm 2	123,777	2,812,361	41,738	21,276	74.8%	74.6%	99.2%	99.2%	85.3%	85.2%	85.5%	85.2%	0.05	0.79	0.74
Algorithm 3	123,695	2,813,530	41,820	20,107	74.7%	74.5%	99.3%	99.3%	86.0%	85.8%	86.2%	85.8%	0.05	0.79	0.74
Algorithm 4	123,485	2,816,705	42,030	16,932	74.6%	74.4%	99.4%	99.4%	87.9%	87.8%	88.1%	87.8%	0.05	0.80	0.74
Algorithm 5	151,751	2,127,217	13,764	706,420	91.7%	91.6%	75.1%	75.0%	17.7%	17.6%	17.8%	17.6%	0.29	0.22	0.67
Algorithm 6	123,695	2,813,530	41,820	20,107	74.7%	74.5%	99.3%	99.3%	86.0%	85.8%	86.2%	85.8%	0.05	0.79	0.74
Algorithm 7	145,617	2,595,431	19,898	238,206	88.0%	87.8%	91.6%	91.6%	37.9%	37.8%	38.1%	37.8%	0.13	0.49	0.80
Algorithm 8	123,612	2,815,897	41,903	17,740	74.7%	74.5%	99.4%	99.4%	87.4%	87.3%	87.6%	87.3%	0.05	0.80	0.74
Algorithm 9	123,415	2,817,411	42,100	16,226	74.6%	74.4%	99.4%	99.4%	88.4%	88.2%	88.5%	88.2%	0.05	0.80	0.74
Algorithm 10	145,617	2,595,431	19,898	238,206	88.0%	87.8%	91.6%	91.6%	37.9%	37.8%	38.1%	37.8%	0.13	0.49	0.80
Algorithm 11	123,612	2,815,897	41,903	17,740	74.7%	74.5%	99.4%	99.4%	87.4%	87.3%	87.6%	87.3%	0.05	0.80	0.74
Algorithm 12	123,415	2,817,411	42,100	16,226	74.6%	74.4%	99.4%	99.4%	88.4%	88.2%	88.5%	88.2%	0.05	0.80	0.74
Algorithm 13	149,447	2,156,696	16,068	676,941	90.3%	90.1%	76.1%	76.1%	18.1%	18.0%	18.2%	18.0%	0.28	0.23	0.66
Algorithm 14	150,434	1,559,091	15,081	1,274,546	90.9%	90.7%	55.0%	55.0%	10.6%	10.5%	10.6%	10.5%	0.48	0.10	0.46
Algorithm 15	49,472	2,816,364	116,043	17,273	29.9%	29.7%	99.4%	99.4%	74.1%	73.8%	74.5%	74.1%	0.02	0.41	0.29
Algorithm 16	155,540	1,513,000	9,975	1,320,637	94.0%	93.9%	53.4%	53.3%	10.5%	10.5%	10.6%	10.5%	0.49	0.10	0.47
Algorithm 17	119,807	2,818,453	45,708	15,184	72.4%	72.2%	99.5%	99.5%	88.8%	88.6%	88.9%	88.6%	0.05	0.79	0.72

Reference standard: the specific health checkups in Japan ( $n = 165,515$ ); total patients  $n = 2,999,152$ . 95% CI; 95% confidence interval; FN, false negative (the number of people for whom reported not having been prescribed diabetic medication, and recorded having been prescribed them); FP, false positive (the number of people for whom reported having been prescribed diabetic medication, and recorded not having been prescribed them); Kappa, Kappa Index; NPV, negative predictive value; PPV, positive predictive value, Prevalence estimate, prevalence of diabetes in the specific health checkups; TN, true negative (the number of people for whom reported not having been prescribed diabetic medication, and recorded not having been prescribed them); TP, true positive (the number of people for whom reported having been prescribed diabetic medication, and recorded having been prescribed them); Youden, Youden Index.

treated.<sup>19</sup> It should be noted that our algorithms with medication codes could only identify patients with diabetes who have been prescribed antidiabetic drugs. Third, we used specific health checkup data as a reference standard. Misclassifications might have occurred in the judgment of the reference standards. In particular, there were patients with diabetes who could not be judged only by specific health checkups, which might have overestimated the false positives cases and underestimated the PPVs. However, there is no perfect reference standard, and it is best to use specific health checkups as a reference standard, which includes blood test and fundus test results.

In conclusion, algorithms 9 and 12 yielded a diagnosis that agrees with specific health checkups results according to specificity, PPV and Kappa Index. In future claims database studies, these validated algorithms will be useful as diagnostic criteria for diabetes.

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Informed Consent: N/A

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Animal Studies: N/A

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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** | Diagnosis related-codes for diabetes.

**Table S2** | Medicine codes for diabetes.

**Table S3** | Medical action codes related to diabetes.

**Table S4** | Raw data for making original algorithms for diabetes in future administrative claims database study.

**Table S5** | Raw data including specific health checkups for making original algorithms for diabetes in future administrative claims database studies