

# Identification of undiagnosed diabetes and quality of diabetes care in the United States: cross-sectional study of 11.5 million primary care electronic records

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## Abstract

**Background:** Electronic diabetes registers promote structured care and enable identification of undiagnosed diabetes, but they require consistent coding of the diagnosis in electronic medical records. We investigated the potential of electronic medical records to identify undiagnosed diabetes and to support diabetes management in a large primary care population in the United States.

**Methods:** We conducted a cross-sectional study and retrospective observational cohort analysis of primary care electronic medical records from a nationally representative US database (GE Centricity). We tested the feasibility of identifying patients with undiagnosed diabetes by applying simple algorithms to the electronic medical record data. We compared the quality of care provided to patients in the United States who had diabetes (coded and uncoded) for at least 15 months with the quality of care provided in England using a set of 16 indicators.

**Results:** We included 11 540 454 electronic medical records from more than 9000 primary care clinics across the United States. Of the 1 110 398 records indicating diagnosed diabetes, only 61.9% contained a diagnostic code. Of the 10 430 056 records for nondiabetic patients, 0.4% ( $n = 40\,359$ ) had at least 2 abnormal fasting or random blood glucose values, and 0.2% ( $n = 23\,261$ ) of the remaining records had at least 1 documented glycosylated hemoglobin (HbA1c) value of 6.5% or higher. Among the 622 260 patients for whom information on quality-of-care indicators was available, those with a coded diagnosis of diabetes had a significantly higher level of quality of care than those with uncoded diabetes ( $p < 0.01$ ); however, the quality of care was generally lower than that indicated in England.

**Interpretation:** We were able to identify a substantial number of patients with uncoded diabetes and probable undiagnosed diabetes using simple algorithms applied to the primary care electronic records. Electronic coding of the diagnosis was associated with improved quality of care. Electronic diabetes registers are underused in US primary care and provide opportunities to facilitate the systematic, structured approach that is established in England.

The US Centers for Disease Control and Prevention has estimated that diabetes affects 12.3% of the US population over 20 years of age and that it goes undiagnosed in 27.8% of people of all ages with diabetes.<sup>1</sup> The economic consequences of the diabetes epidemic are high, with an estimated societal cost to the United States of diagnosed diabetes of \$245 billion in 2012.<sup>2</sup> This represents a rise of 41% since a previous study in 2007,<sup>3</sup> which estimated an additional annual cost of \$18 billion for undiagnosed diabetes. Strategies to improve detection are clearly needed, because prompt diagnosis is a prerequisite to high-quality diabetes care.

For people in whom diabetes has been diagnosed, a variety of quality-of-care indicators have been developed and widely disseminated.<sup>4</sup> With the increasing adoption of electronic medical record systems across the US, it should be ever more feasible to use electronic medical record databases to monitor and possibly

improve care processes and clinical outcomes.<sup>5</sup> Such a model exists in England, where performance of general practitioners against a set of quality-of-care indicators is assessed and published annually.<sup>6</sup> This approach is dependent on the creation and maintenance of electronic diabetes registers, which form the basis for recall, audit and point-of-care reminders. Application of

**Competing interests:** Candace Gunnarsson reports being the president of S2 Statistical Solutions, a paid consultant to the study sponsor. Paul Cload was an employee of GE Healthcare during the study. Susan Ross served as an independent consultant to S2 Statistical Solutions. No other conflicts were declared.

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an electronic code for diabetes automatically enters a patient into the register and is the most basic requirement for structured, proactive care under this model. Linkage to payments motivates practices in England to use codes consistently, which provides high-quality, population-level data about the quality of care.

Our objectives in this study were threefold. First, we investigated the prevalence of an electronic code for diabetes in records for people with known, diagnosed diabetes identified either by these codes or by use of diabetes-specific medication. Second, we sought to test the feasibility of detecting patients with undiagnosed diabetes by applying various algorithms to electronic medical record data derived from a nationally representative sample of US primary care practices. Finally, we quantified the extent to which the care of diabetic patients satisfied a range of quality indicators (both process and intermediate outcome measures) for diabetes care overall, regionally and relative to results in England. We also compared the quality of care provided to patients with and without an electronic code for diabetes in their record.

## Methods

### Study design

The study design was a retrospective observational cohort analysis within a large cross-sectional study.

### Sources of data

The US data were obtained from the GE Centricity electronic medical record database. Centricity is an electronic medical record system and a commercial product of GE Healthcare

that supports the routine care of patients managed in primary care, including those with chronic conditions. It is one of a number of options for office-based practices adopting electronic medical record systems, an increasing tendency during the past decade.<sup>7</sup> The Centricity database contains longitudinal patient records from more than 9000 primary care clinics and 11 million patients with private or public insurance coverage. The database tends to include the larger primary care practices in the US and was current to Sept. 1, 2009, at the time of analysis. Although broadly representative of national norms, the database contained a higher proportion of visits by younger patients and by females when compared with National Ambulatory Medical Care Survey (NAMCS) data reported in 2010 (Table 1).<sup>8</sup> The Centricity database appeared to be more sensitive at capturing diagnoses, especially diagnoses of chronic diseases, than the NAMCS database.

All available records were included in the cross-sectional study, which examined the prevalence of undiagnosed diabetes. For the observational cohort analysis, which investigated quality of care, we included only electronic records in which the onset of diabetes occurred at least 15 months before the last visit on record.

For the analysis of quality of care in England, we obtained Quality and Outcomes Framework data for the period April 2009 to March 2010 from the UK Health and Social Care Information Centre's Quality Management Analysis System.<sup>9</sup> This national system extracts content from medical records from 8293 general practices in England and represents the majority of the English population. We did not include Quality and Outcomes Framework data from other UK countries in this analysis.

**Table 1: Number of visits in the Centricity database (current study) and the National Ambulatory Medical Care Survey (NAMCS) database (taken from Crawford et al.<sup>8</sup>), by sex and age group**

Sex; age, yr	No. of visits per 100 person-years	
	NAMCS database <i>n</i> = 963 617	Centricity database <i>n</i> = 6 202
<b>Female</b>	376.8	483.3
< 15	245.7	380.3
15–24	220.0	392.9
25–44	313.0	401.1
45–64	446.9	426.3
65–74	671.3	519.5
≥ 75	784.6	569.5
<b>Male</b>	283.1	403.1
< 15	282.9	386.0
15–24	125.1	279.1
25–44	177.5	343.8
45–64	332.7	396.3
65–74	618.6	481.0
≥ 75	741.4	543.2

### Prevalence of uncoded diabetes

We identified electronic medical records that either had a diagnostic code for diabetes or indicated use of diabetes-specific medications (sulfonylureas, biguanides, thiazolidinediones or insulin). We excluded patients with a diagnosis of polycystic ovary syndrome, because metformin may be prescribed for this condition. We determined the proportion of electronic records that had a diagnostic code, the proportion identified purely on the basis of medication use and the proportion in which both were recorded.

### Detection of undiagnosed diabetes

We tested 3 modifications of an algorithm widely used in the United Kingdom to identify patients with undiagnosed diabetes.<sup>10</sup>

In one modification, all patients were excluded from the dataset if they had a diagnosis of diabetes, prediabetes, impaired glucose tolerance or gestational diabetes (International Classification of Diseases, 9th revision [ICD-9] codes 249.xx, 250.xx, 790.21, 790.22, 790.29 and 648.83) or if their electronic record indicated use of diabetes-specific medication (as defined earlier). Among the remaining patients in the dataset, we examined all recorded glucose levels. We considered a random blood glucose level of 11.1 mmol/L or higher or a fasting blood glucose level of 7.0 mmol/L or higher to be abnormal. Patients with at

least 2 abnormal glucose results on record were considered to have potentially undiagnosed diabetes.

In the second modification, we identified patients who had no evidence of diagnosed or undiagnosed diabetes, as defined by the conditions above, but who had a glycated hemoglobin (HbA<sub>1c</sub>) value of 6.5% or higher on record. These patients were also deemed to have potentially undiagnosed diabetes, based on the American Diabetes Association recommendations regarding diagnosis of diabetes using HbA<sub>1c</sub> measurements<sup>11</sup> as well as on findings of a population-based study suggesting that HbA<sub>1c</sub> may be a more sensitive signal of undiagnosed diabetes than fasting blood glucose levels.<sup>12</sup>

In the third modification, the algorithm was set up to find patients whose undiagnosed diabetes was detected by abnormal glucose levels on record as well as those identified only by their HbA<sub>1c</sub>. This approach offered the most inclusive means of detecting undiagnosed diabetes.

The geographic distribution of undiagnosed diabetes as a proportion of all people with diabetes (diagnosed and undiagnosed) was computed. We mapped the results using the first 3 digits of the zip codes to group practices into 137 “zip-3” areas, and 4 main geographic regions in the US (northeast, south, midwest and west).

### Assessment of quality of care

To assess the quality of diabetes management, we selected 16 quality-of-care indicators, representing both process and intermediate outcome measures, from the UK’s Quality and Outcomes Framework guide for 2009/10.<sup>13</sup> These indicators are similar to the diabetes monitoring recommendations of

the American Diabetes Association.<sup>4</sup> We calculated the proportion of all patients with diabetes who satisfied each of the indicators in the 15 months before their last visit on record. Proportions were calculated by US region and were compared with the Quality and Outcomes Framework results for England for the period April 2009 to March 2010. We also examined the achievement of quality-of-care indicators among patients in the US cohort with coded diabetes who were using diabetes medication and compared it with that among patients with uncoded diabetes who were using diabetes medication.

### Statistical analysis

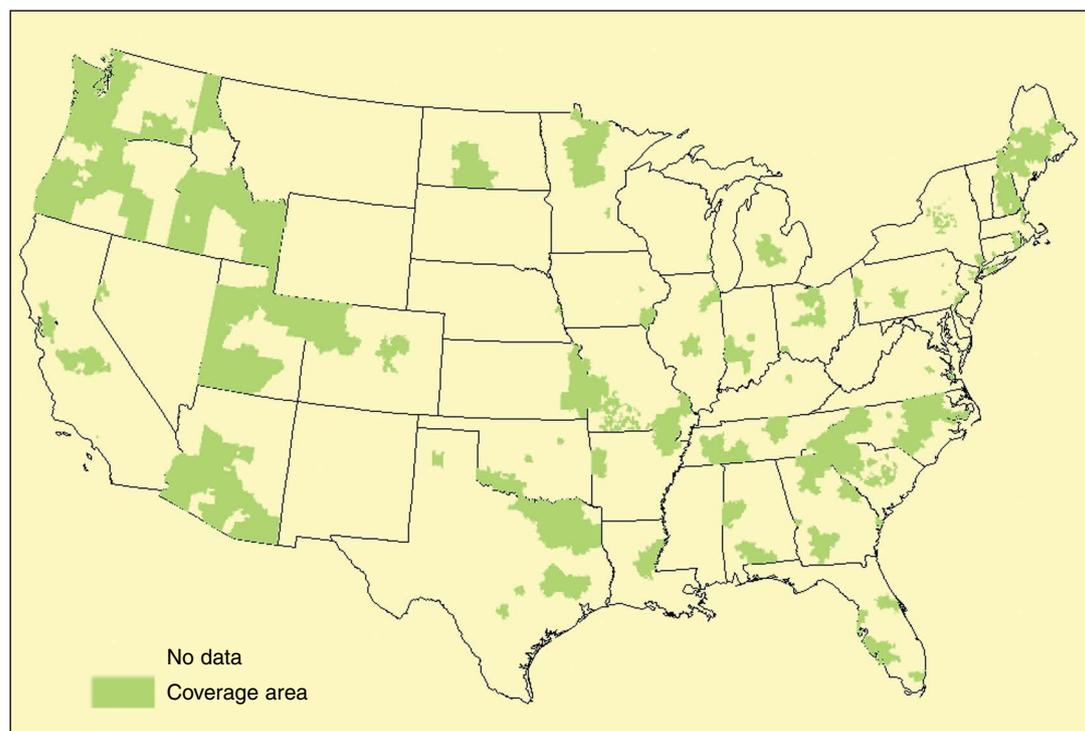
We compared the achievement of quality-of-care indicators in different patient subgroups (including uncoded diabetes, coded diabetes and all diabetes). The  $\chi^2$  test was used to measure differences in proportions and to calculate *p* values for significance. All analyses were performed with SAS Version 9.1 (SAS Institute).

### Ethics approval

Because we used only anonymized patient data, an informed consent exemption was obtained from the New England Institutional Review Board.

### Results

The study sample included a total of 11 540 454 electronic records from more than 9000 primary care practices distributed across the US (Figure 1).



**Figure 1:** Distribution of more than 9000 primary care practices across the United States contributing data from electronic medical records for 11 540 454 patients to the GE Centricity database as of Sept. 1, 2009.

### Prevalence of uncoded diabetes

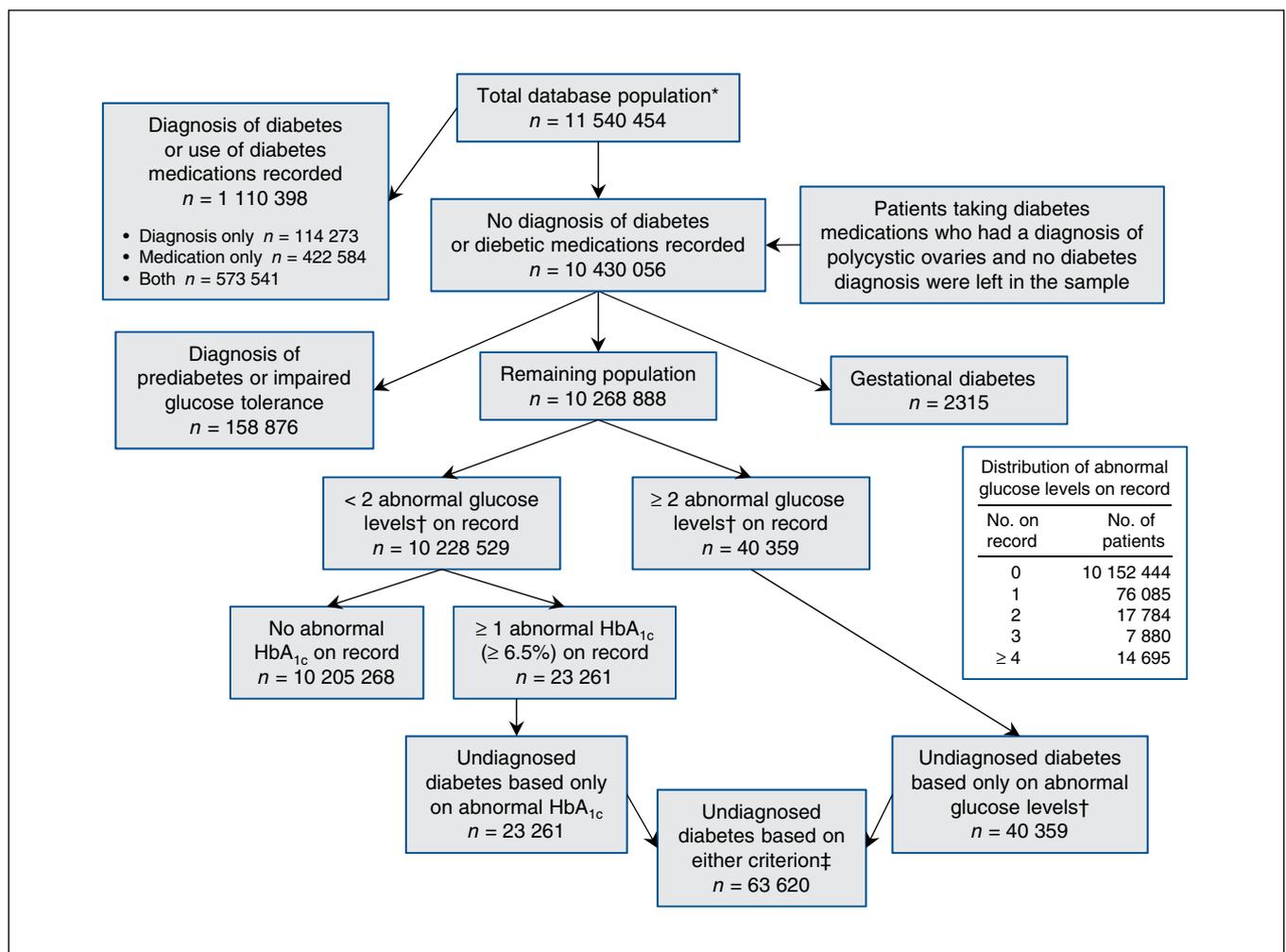
Of 1 110 398 records indicating diagnosed diabetes, 422 584 (38.1%) were identified on the basis of medication use (i.e., no diabetes code was present) (Figure 2). Only 61.9% of the diabetes population had a coded diagnosis and thus were in an electronic diabetes register in primary care. This approach will have missed patients with uncoded diabetes who were not receiving medication.

### Detection of undiagnosed diabetes

After we removed all patients with a coded diagnosis of diabetes or a prescription for diabetes medications, as well as patients with diagnostic codes for prediabetes, impaired glucose tolerance or gestational diabetes, a total of 10 268 888 patients remained in the database (Figure 2). Of these, 0.4% ( $n = 40\,359$ ) had at least 2 abnormal glucose levels on record. Of the 10 228 529 remaining patients with 1 or no abnormal levels on record, 0.2% ( $n = 23\,261$ ) had at least 1 elevated HbA<sub>1c</sub> recorded. Thus, up to 0.6% of all nondiabetic patients in the database appeared to have undiagnosed diabetes on the

basis of abnormal blood test results alone (Figure 2). The prevalence of undiagnosed diabetes identifiable in this way increased with age, exceeding 1% among patients 65 years of age or older, and exceeding 2% among those 75 years or older. There did not appear to be any sex-related imbalances in these prevalence estimates (data not shown).

The total number of patients with diabetes, including potentially undiagnosed diabetes, was therefore 1 174 018, of whom 63 620 (5.4%) had undiagnosed diabetes. When we explored the distribution of patients with undiagnosed diabetes by geographic region, several “hot spots” were noted (Figure 3). Among all patients with diabetes (diagnosed and undiagnosed), the proportion with undiagnosed diabetes was higher in certain areas in Arizona, North Dakota, Minnesota, South Carolina and Indiana compared with other locations. We did not perform further explorations of prevalence of undiagnosed diabetes at the individual practice level, because our analysis was not intended to be a performance measurement evaluation. No adjustments were made for possible variations in case-mix across geographic regions.



**Figure 2:** Identification of patients with undiagnosed diabetes based on biochemical data in electronic medical records. \*As of Sept. 1, 2009. †Random blood glucose level  $\geq 11.1$  mmol/L or fasting blood glucose level  $\geq 7.0$  mmol/L. ‡Patients with  $\geq 2$  abnormal glucose levels on record or  $\geq 1$  abnormal glycated hemoglobin (HbA<sub>1c</sub>) value on record.

### Quality of diabetes management

Of all patients in the database, 1 110 398 (9.6%) had diabetes as defined by a diagnostic code or medication use. Of these, 622 260 had known diabetes for at least 15 months before the last visit on record. Within this patient subgroup, we calculated the proportion who satisfied various clinical indicators of quality of care. In Table 2, the proportions are shown for all patients with diabetes and for those identified by diagnostic code or by medication use. Comparable results for all patients with diabetes in general practices in England are also shown. All of the between-column comparisons were significant ( $p < 0.01$ ).

Of the 622 260 records included in this analysis, only 59.2% showed HbA<sub>1c</sub> testing at any time in the 15 months before the last visit. A documented HbA<sub>1c</sub> value at goal ( $\leq 7.0\%$ ) was documented in only 33.8% of the records, which suggests either suboptimal control or no monitoring in the interval of interest. In some cases, a less stringent, individualized target may have been set. Body mass index was recorded in only 57.3% of the records in the interval studied. With regard to blood pressure, 88.0% of the patients had a measurement on record in the last 15 months, but only 67.6% of patients had a blood pressure of 145/85 mm Hg or lower. The level of achievement of these quality-of-care indicators was in all but one case significantly lower in the subgroup whose diabetes was identified by medication use only.

The proportions of patients in England for whom these care indicators were achieved are shown in Table 2. For all of the indicators except one (use of angiotensin-converting-

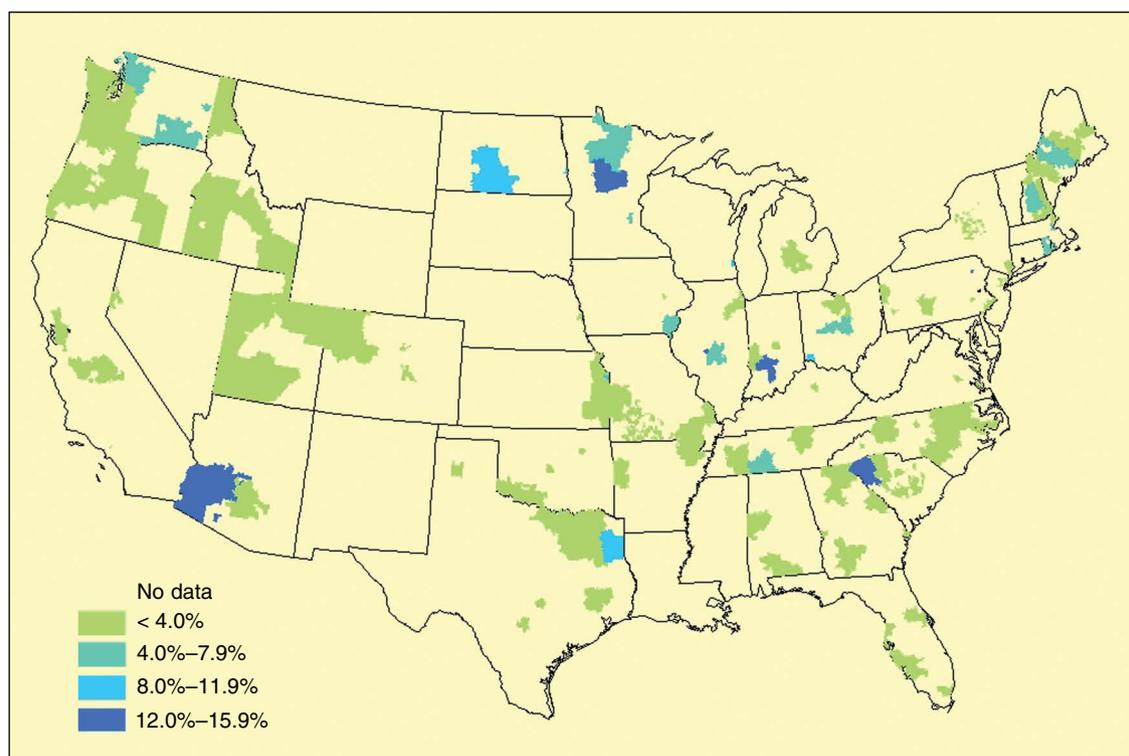
enzyme inhibitors or angiotensin-receptor blockers), practitioners in England appeared to be performing better than their US counterparts in any region, by wide margins in many instances.

Figure 4 displays performance in the US by major region. Data were unavailable for 4 of the indicators (record of presence or absence of peripheral pulses, neuropathy testing, retinal screening and immunization vaccination). The northeast region had the highest levels of achievement for most of the indicators, although the observed differences were relatively small, except for treatment with angiotensin-converting-enzyme inhibitors or angiotensin-receptor blockers. The mid-west region, on the other hand, had the poorest performance, with the lowest levels of achievement in 10 of the 12 indicators studied.

### Interpretation

We were able to identify a substantial number of people with probable undiagnosed diabetes in the US based on existing biochemical evidence in their electronic medical records. In some areas of the country, this amounted to 12.0%–15.9% of the overall diabetes population. Although this is less than the 27.8% believed to have undiagnosed diabetes,<sup>1</sup> these people were immediately identifiable through simple searches of electronic medical records from primary care practices.

Whether fasting blood glucose, random blood glucose or HbA<sub>1c</sub> values are used, the detection of diabetes is a prerequisite to high-quality care. Our results suggest a need for



**Figure 3:** Distribution of patients with undiagnosed diabetes in the total diabetes population (diagnosed and undiagnosed,  $n = 1\,174\,018$ ) in “zip-3” areas (areas defined by the first 3 digits of the zip codes for group practices).

heightened recognition and follow-up of these signals in patients not known to have diabetes. Measurement of HbA<sub>1c</sub> offers an immediately actionable way to improve detection of this condition. Elevated HbA<sub>1c</sub> values have been independently associated with increased cardiovascular risk among people without diabetes,<sup>14</sup> as well as with reduced survival among those with diabetes.<sup>15</sup>

Our findings suggest that little changed in the quality of diabetes care in the 7 years following the National Health and Nutrition Examination Survey III analysis reported in 2002,<sup>16</sup> despite rapidly improving information technology to support chronic disease management. However, it is impossible to draw firm conclusions about the apparent gap between recommended and actual practice, because a proportion of patients in our study would have received at least some of their diabetes care from specialists outside the electronic medical record system. Nevertheless, it should be noted that others have reported similar gaps.<sup>17</sup> Despite the finding in a pre-

vious report that the Centricity database was sensitive to the capture of chronic disease diagnoses,<sup>8</sup> there still appears to be substantial scope for improving the quality of diabetes coding.

UK general practitioners have the responsibility for providing comprehensive care and for assuring a minimum standard of quality achievement (evidenced by the data captured in the UK electronic medical records), regardless of whether the patient is also receiving diabetes care from a specialist. This resonates with the North American concept of the “medical home,” an approach that promotes team-based responsibility for continuous, coordinated care led by a personal physician, whether a generalist or a specialist. Interestingly, from an early stage, the importance of using health records is identified as a key organizational principle of this concept.<sup>18</sup>

### Limitations

We compared the US results with those derived from primary care practices in England, but the context-dependency

**Table 2: Proportion of patients with diabetes in the United States and England whose electronic medical records indicated achievement of selected quality-of-care indicators within the 15 months before the last visit on record**

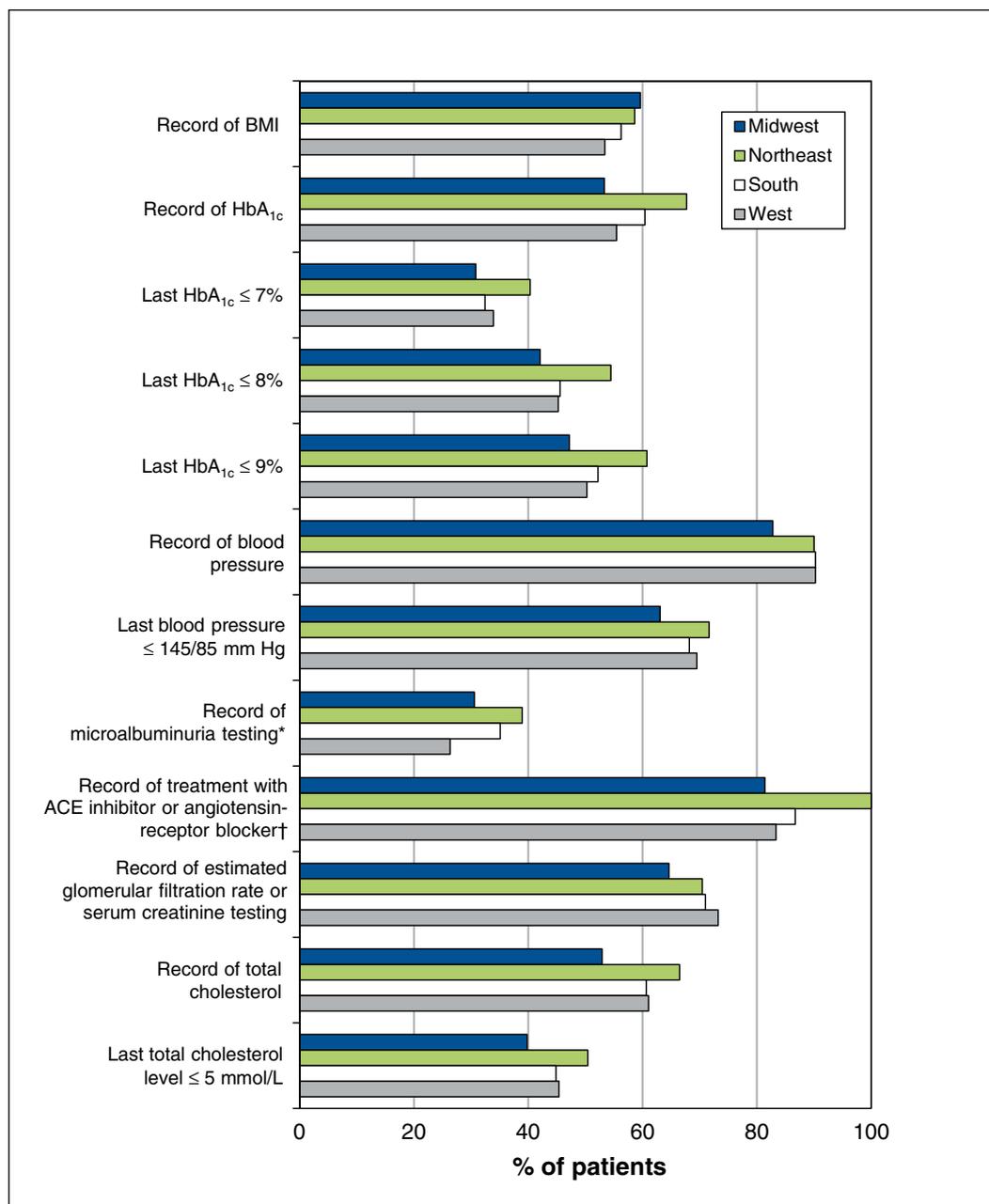
Quality-of-care indicator	% of patients*				
	United States				England† n = NA
	Total n = 622 260	Coded diagnosis only n = 56 492	Medication use only n = 228 926	Coded diagnosis and medication use n = 336 842	
Record of BMI	57.3	54.2	49.2	63.4	94.7
Record of HbA <sub>1c</sub>	59.2	49.8	40.4	73.5	97.2
Last HbA <sub>1c</sub> ≤ 7%	33.8	45.9	23.8	38.6	53.8
Last HbA <sub>1c</sub> ≤ 8%	46.4	48.8	32.4	55.5	77.4
Last HbA <sub>1c</sub> ≤ 9%	52.3	49.3	36.1	63.7	88.0
Record of the presence or absence of peripheral pulses	NR	NR	NR	NR	91.1
Record of neuropathy testing	NR	NR	NR	NR	90.8
Record of retinal screening	NR	NR	NR	NR	90.9
Record of blood pressure	88.0	86.7	81.5	92.7	98.3
Last blood pressure ≤ 145/85 mm Hg	67.6	66.9	62.1	71.4	80.6
Record of microalbuminuria testing (among patients without proteinuria)	33.4	24.5	21.4	43.0	88.5
Record of treatment with ACE inhibitor or angiotensin-receptor blocker (among patients with proteinuria‡ or microalbuminuria)	85.7	57.1	95.0	85.8	80.0
Record of estimated glomerular filtration rate or serum creatinine testing	69.3	70.0	54.1	79.6	97.0
Record of total cholesterol	59.7	61.5	43.5	70.4	96.0
Last total cholesterol level ≤ 5 mmol/L	44.6	41.6	33.0	53.0	83.0
Influenza vaccination in the preceding period Sept. 1 to Mar. 31	NR	NR	NR	NR	90.4

Note: ACE = angiotensin-converting enzyme, BMI = body mass index, HbA<sub>1c</sub> = glycated hemoglobin, NA = not available, NR = not recorded.  
 \*Between-column comparisons are all significant at  $p < 0.01$ .  
 †All patients with diagnostic code for diabetes.  
 ‡Proteinuria defined as albumin (or protein) > 150 mg in a 24-hour collection or > 20 mg/dL protein or > 23 mg albumin in a urine sample.

of these data make cross-national comparisons difficult. Specifically, there are important differences in the way the data were collected. In England, exceptions are allowed for inclusion of patient data. The median rate of exception reporting varied from 1.1% to 13.5% depending on the diabetes indicator, with a median overall rate of 4.7% during the study period.<sup>13</sup> With the US data, we could not analyze frequencies of clinical examinations of foot pulses, retinopathy or peripheral neuropathy screening, because such data are not routinely recorded in the Centricity electronic medical

record system; instead, they are entered as free-form text fields in the medical record. It was also not possible to ascertain accurately the extent of vaccinations received by patients, since they have many options for receiving vaccinations outside of their primary care practitioner's office setting.

General practitioners in England are using electronic medical record systems that support systematic, automated recall and audit as well as point-of-care screen reminders. These capabilities of electronic medical records have not yet been



**Figure 4:** Proportion of patients with diabetes whose electronic medical record indicated achievement of clinical quality-of-care indicators, by US region. \*Among patients without proteinuria. †Among patients with proteinuria or microalbuminuria (proteinuria defined as albumin [or protein] > 150 mg in a 24-hour collection or > 20 mg/dL protein or > 23 mg albumin in a urine sample). ACE = angiotensin-converting enzyme, BMI = body mass index, HbA<sub>1c</sub> = glycated hemoglobin

adopted in many US practices.<sup>7</sup> In England, payments to general practitioners are linked in part to their performance against quality-of-care indicators. In the US, pay-for-performance implementation is variable, and primary care practitioners using the GE electronic medical record system may defer responsibility for diabetes care and monitoring to specialist colleagues outside the system. It is possible that patients without a diabetes diagnostic code in the Centricity database, if receiving care elsewhere, are achieving higher quality care than we have estimated. Because specialist records were not included in the US data we analyzed, the Quality and Outcomes Framework data from England were deemed the most appropriate comparator, as opposed to data from other UK sources such as the National Diabetes Audit,<sup>19</sup> which includes specialist care. It is also possible that US patients without insurance may choose not to see a physician, which leads to lack of representation in such a database and introduces an additional bias, but in the opposite direction, toward under-recognition of suboptimal care.

## Conclusion

We were able to identify a substantial number of patients with uncoded diabetes and probable undiagnosed diabetes based on existing biochemical evidence using simple algorithms applied to primary care electronic records. Patients with a coded diagnosis of diabetes had a higher quality of care than those with uncoded diabetes. Organizational context may determine the potential for using primary care records to identify undiagnosed diabetes and to monitor quality of diabetes care. But wherever electronic diabetes registers are used to support the provision of care, and where blood glucose levels, HbA<sub>1c</sub> and quality-of-care data are recorded in the same system, it should be possible to identify readily (and at low cost) individuals at risk of their diabetes going undetected and those receiving suboptimal care. This applies across all nations using electronic medical record systems, including Canada. The use of electronic diabetes registers is central to this opportunity.

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**Contributors:** Tim Holt participated in the study concept and design, analysis and interpretation of the data, and drafting of the manuscript. Candace Gunnarsson had full access to all of the data in this study. She was involved in the study concept and design, along with the drafting of the manuscript and all statistical analysis and study supervision. Paul Cload participated in the study concept and design, the acquisition of the data and the drafting of the manuscript. Susan Ross contributed to the literature search and review, the protocol development and study design, the interpretation of the data and the drafting of the manuscript. All of the authors approved the final version of the manuscript submitted for publication and agreed to act as guarantors of the work.

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