

Outpatient Diagnostic Errors: Unrecognized Hyperglycemia

ORIGINAL ARTICLE

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CONTEXT. To estimate the prevalence of unrecognized diabetes in a large managed care organization (MCO).

DESIGN. Retrospective data analysis.

PATIENTS AND SETTING. All patients over age 30 enrolled in the (staff-model) MCO of Duke University Medical Center between April 1996 and March 1999.

DATA SOURCES. Merged database of MCO administrative, billing, and laboratory files and selected medical records.

CASE DEFINITIONS. We identified all patients with abnormal test results suggestive of diabetes (i.e., hemoglobin [Hb] A_{1c} ≥ 7.0% or plasma glucose ≥ 200 mg/dL) on one or more occasions. Patients were considered to have recognized diabetes if they had an ICD-9 diagnostic code for diabetes in the administrative database or a diagnosis mentioned in their medical record (on the basis of medical record review of a random sample of 30% of patients with abnormal test results and no ICD-9 code). Patients with unrecognized diabetes did not have an ICD-9 code or a medical record diagnosis.

RESULTS. 1426 patients had laboratory tests suggestive of diabetes. Of these patients, 1122 (79%) had an ICD-9 diagnostic code for diabetes in the administrative database. Forty-six of the remaining 304 patients without ICD-9 codes had mention of diabetes on medical record review; thus, we estimate that as many as 258 (18% of patients with laboratory tests suggestive of diabetes) had unrecognized diabetes. When this estimate was restricted to findings that are most suggestive of diabetes (high HbA_{1c} or two high plasma glucose tests), 124 (9%) patients had unrecognized diabetes.

CONCLUSIONS. A substantial proportion of patients in an MCO have laboratory values suggestive of diabetes with no evidence that their providers have recognized this condition.

In the past few years, researchers and policymakers have paid increasing attention to the issue of medical errors.^{1,2} Several recent studies have detailed the epidemiology and frequency of such errors.^{3–6} Most studies have focused on inpatient errors; the few data on outpatient errors primarily report medication errors.^{6–7} However, outpatient errors, such as failure to diagnose, are also an area of legitimate concern. Such failure is often related to underestimating the seriousness of an indeterminate finding (e.g., a breast “lump”); however, it is also possible for definitive evidence of a condition, such as a grossly abnormal laboratory test value, to go unrecognized by providers.³

The issue of unrecognized abnormal laboratory values may be especially important in diabetes. Many patients with diabetes remain undiagnosed,^{8,9} and treatment of hyperglycemia is known to reduce the development of microvascular complications.^{10,11} In addition, knowledge of diabetes can lead to both more aggressive treatment for

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hypertension and hyperlipidemia to reduce cardiovascular morbidity¹²⁻¹⁶ and to efforts to decrease diabetic complications, such as eye and kidney disease.

This study was designed to estimate the number of patients in a managed care population with unrecognized hyperglycemic laboratory results suggestive of diabetes. An additional objective was to estimate the predictive value of the database in diagnosing diabetes.

Methods

This study was a retrospective analysis of several merged administrative databases of Duke University Medical Center's (DUMC's) managed care organization (MCO). During the time of the study, Duke Managed Care was a staff-model MCO run in conjunction with DUMC.

Data Sources

The primary database for the study analyses was generated by merging the managed care administrative databases; the billing data from the MCO; and the DUMC laboratory database, which records more than 96% of Duke Managed Care laboratory tests. We also reviewed the medical records of selected patients.

Patients

Patients from the database were entered into the analysis if, at any time between April 1996 and March 1999, they had either an ICD-9 diagnostic code for diabetes (ICD-9 250.0 to 250.9) or if they had abnormal results on laboratory glycemic testing. Laboratory tests used for the study were plasma glucose tests and hemoglobin A_{1c} (HbA_{1c}) measurements. Glucose values were treated as random unless they were recorded in the database as postprandial values in an oral glucose tolerance test or as fasting. By these criteria, 99% of the glucose values in the data set were considered random.

Unrecognized Diabetes

The primary analysis was designed to estimate the number of patients with abnormal glycemic test results suggestive of diabetes who had no evidence of recognized diabetes. For this analysis, "abnormal" was defined by any one of three criteria: HbA_{1c} 7.0% or higher, plasma glucose 200 mg/dL or higher, or plasma glucose 126 mg/dL or higher if the laboratory value was denoted as fasting in the database. We chose a cut-off point of 7.0% for HbA_{1c} because the test is 99% specific for the presence of diabetes at this level¹⁷ and this is the level at which diabetes is considered to require clinical action according to evidence-based guidelines.¹⁸ We then

searched for an ICD-9 code for diabetes for patients who met this criteria.

We considered patients to have recognized diabetes if they had an ICD-9 code of 250.0 to 250.9 in the administrative database or if diabetes was mentioned in their medical record. To categorize patients, we identified those without ICD-9 codes as candidates for medical record review. We then reviewed a 30% random sample of these charts. A single examiner searched all progress notes for the word "diabetes" or "DM." Extrapolation from the 30% sample was performed to estimate the final number of patients with unrecognized hyperglycemia suggestive of diabetes.

Accuracy of ICD-9 Codes

The secondary analysis was designed to estimate the accuracy of the ICD-9 codes 250.0 to 250.9 in our administrative database. We searched for laboratory results for all patients with a diagnostic code for diabetes. Compared with the primary analysis, the requirements of the secondary analysis for abnormal glycemic testing were reduced (HbA_{1c} \geq 6.0% or plasma glucose 126 mg/dL or higher). Patients with an ICD-9 code for diabetes and abnormal glycemic testing were presumed to have diabetes. Patients with an ICD-9 code for diabetes and normal or absent laboratory data were candidates for medical record review, and a random 30% sample of these charts were reviewed. Patients with an ICD-9 code for diabetes, but normal or absent laboratory data and no mention of diabetes in the medical record, were considered to have a false-positive code for diabetes.

Analysis

We report estimated rates of unrecognized hyperglycemia suggestive of diabetes and false-positive codes for diabetes. Chi-square analysis was performed to assess the difference in rates of various tests being unrecognized. All analyses were performed using the SAS analysis system (SAS Institute, Cary, NC).

Results

Demographic characteristics of the study patients are shown in **Table 1**. Sixty-one percent of patients were female, 74% were Caucasian, and the mean age was 51 years (SD \pm 13), with 18% 65 years or older.

Unrecognized Diabetes

Of the 22,169 patients in DUMC, 1426 had laboratory data suggestive of diabetes (**Figure 1**). Of those patients with abnormal tests, 1122 (79%) had an ICD-9 code for diabetes in their administrative record. Diabetes was

TABLE 1
Characteristics of the Study Population

CHARACTERISTIC	PERCENTAGE OF THE POPULATION
Age	
30–44 yr	46%
45–54 yr	25%
55–64 yr	11%
65–74 yr	6%
75+ yr	12%
Race	
White	74%
African American	23%
Asian/Pacific Islander	2%
Native American	1%
Sex	
Female	61%

mentioned on the medical records of 46 of the remaining 304 patients without ICD-9 codes. Based on the 30% of medical records reviewed, we estimated that 18% of patients with abnormal test results had unrecognized diabetes. Elevated plasma or fasting glucose levels were more likely to go unrecognized than elevated HbA_{1c} values (72% of patients had unrecognized diabetes on the basis of elevated glucose vs. 28% on the basis of elevated HbA_{1c} [$P < 0.001$]).

Because a single high glucose value is inadequate to definitively diagnose diabetes and could be a laboratory error, we further examined the patterns of abnormal test results. Among the patients with hyperglycemia diagnosed on the basis of an initial high glucose value, 52 had a second glucose value greater than 200 mg/dL, 75 had a second abnormal value that did not meet our threshold (random glucose between 126 and 199 mg/dL or HbA_{1c} between 6.0% and 6.9%), 25 had a normal second glucose value, and 34 did not have a second glucose test. While second glucose test results were associated with chart mention of diabetes ($P = 0.01$, data not shown), 67% of patients with two glycemic tests suggestive of diabetes and no diabetes diagnostic code had no mention of diabetes on the chart.

Restricting our estimate to cases where we are most confident in a diagnosis of diabetes (high HbA_{1c} or two high glucose tests), 9% had unrecognized diabetes.

Accuracy of ICD-9 Codes

Of the 1384 patients with an ICD-9 code of 250.0 to 250.9, 1194 had abnormal glycemic testing results (Figure 2). Of the remaining 190 patients, we estimate

that 110 (58%) had the diagnosis of diabetes in their medical record based on the 30% random sample selected for medical record review. Therefore, the positive predictive value of a 250.0 to 250.9 code for the diagnosis of diabetes was approximately 0.94 (1304/1384).

Discussion

Data from this study show a substantial proportion of patients in whom the diagnosis of diabetes is suggested by laboratory data, but for whom there is no evidence, either from billing data or medical records, that the condition was recognized. These patients may represent at least 9% and as many as 18% of all patients with diabetes, and nearly 1% of adults covered by the MCO.

Why are so many patients with very elevated glycemic test results unrecognized as having diabetes? Clues to the answer to this question lie in the fact that elevated glucose levels were much more likely to be “missed” than elevated HbA_{1c} levels. There are at least two settings in which a glucose test is ordered without interest in the glycemic status of the patient. The first of these occurs when a chemistry panel is ordered because another element of the panel (not glucose) is of interest (e.g., serum creatinine for a patient with hypertension). The provider may consider only the value that was of initial interest and not the glucose level. The second situation occurs when a panel is ordered for a routine evaluation (e.g., “baseline,” “pre-op”) by a provider who would not ordinarily manage diabetes (anesthesiologist, emergency room physician). If laboratory results are automatically returned only to the ordering physician and not to the primary care provider, it is possible that no action may be taken on the abnormal laboratory result.

Our secondary finding is that ICD-9 codes specific to diabetes in the Duke Managed Care administrative database appear to have approximately a 94% predictive value for the diagnosis of diabetes. However, when glycemic test data are either normal or absent on the basis of chart review, the predictive value of a diagnostic code was only 58% (110/190) (Figure 2). Our data suggest both that administrative data are a useful screen for identifying patients with true diabetes, and that, when available, laboratory data are a crucial confirmatory step for refining diagnostic accuracy. These findings are consistent with a previous report from the United Kingdom, which found a positive predictive value of 0.96 for pooled administrative databases with medical record review as the criterion standard.¹⁹ In that study, laboratory data also added diagnostic certainty.

There are several limitations to our study. We used a conservative cut-off for the diagnosis of unrec-

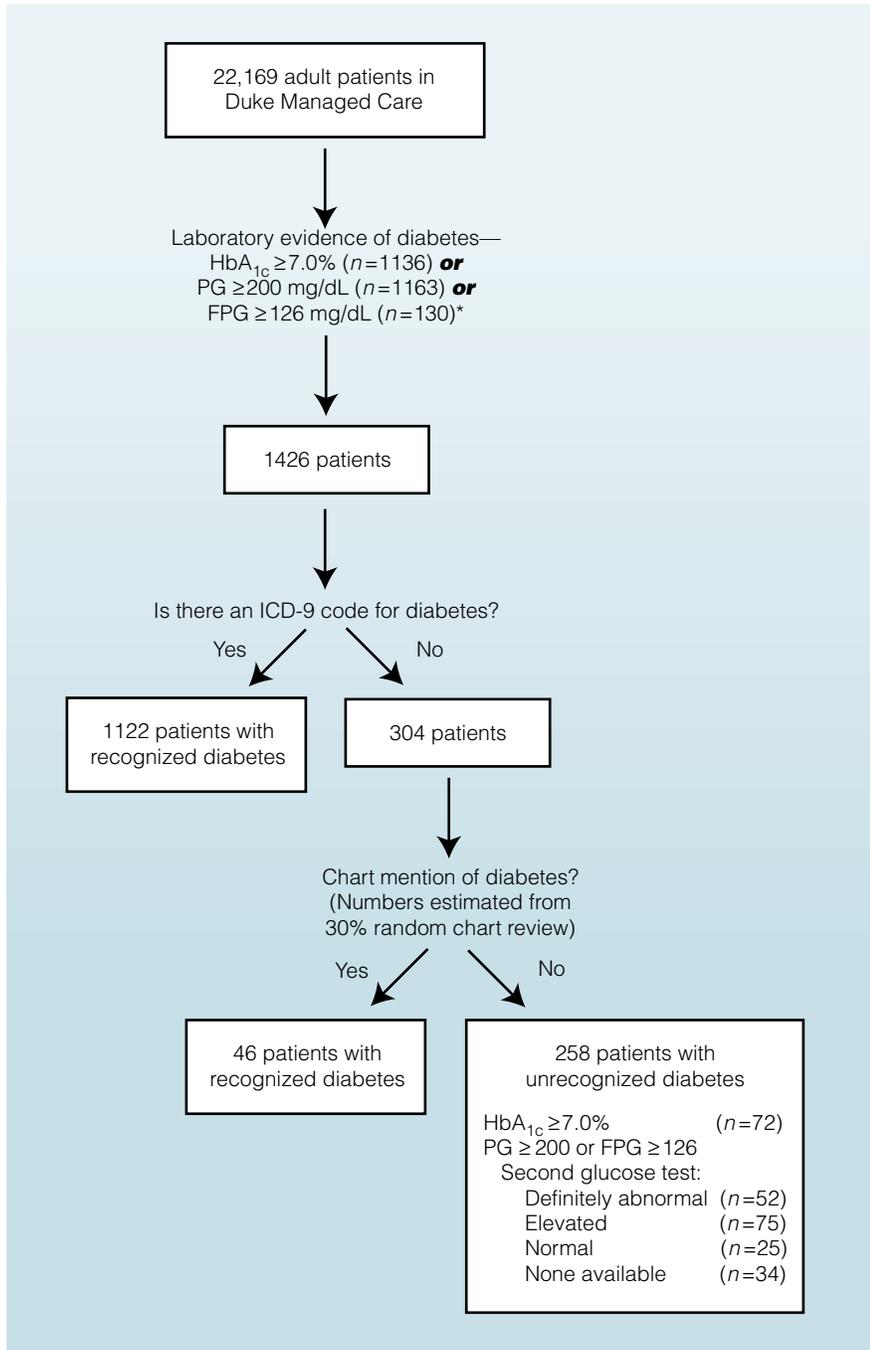


FIGURE 1. Recognition of diabetes.

Diabetes was unrecognized in 18% (258/1426) of patients with laboratory data suggestive of this condition. Numbers of patients do not add up because some patients had multiple unrecognized tests. PG = plasma glucose; FPG = fasting plasma glucose; HbA_{1c} = hemoglobin A_{1c}.

ognized hyperglycemia, which leads to a conservative estimate of the magnitude of the problem of unrecognized diabetes. Some of the 618 patients with glucose values ranging from 126 to 200 mg/dL and no ICD-9 code probably have unrecognized diabetes, but without knowing the fasting status of the patient at the time of the glucose test, we have no accurate way of ascertaining cases of diabetes. However, other limitations lead to a possible overestimate of unrecognized diabetes. First,

despite our best efforts to determine diabetes from the medical record, patients may have been treated for diabetes out of network without mention in the medical record. In addition, the use of a single test as the criterion for unrecognized diabetes may overrepresent the prevalence of unrecognized diabetes, because this makes laboratory error or a stress episode more likely. Also, pharmacy data could not be obtained for these patients; these data would have provided further con-

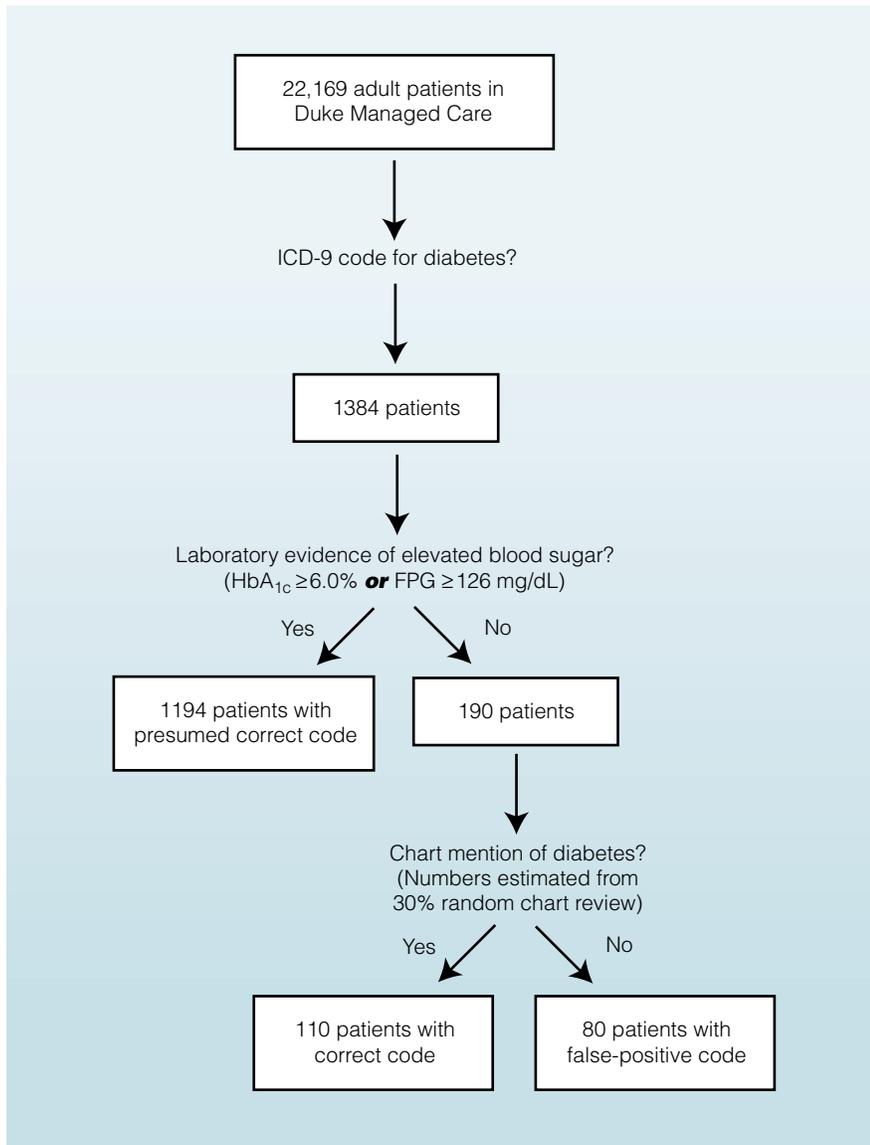


FIGURE 2. Accuracy of ICD-9 coding. Of the 1384 patients with an ICD-9 code for diabetes, all but 80 (6%) had the diagnosis confirmed on the basis of laboratory data or chart review. FPG = fasting plasma glucose; HbA_{1c} = hemoglobin A_{1c}.

firmation of the presence or absence of diabetes. Finally, patients may have been hospitalized in clinically stressful situations (postoperative, intensive care) or taking medications (e.g., corticosteroids) that may cause transient hyperglycemia without the presence of diabetes. These situations may lead to misclassification of these patients as having unrecognized diabetes when they do not have long-term abnormalities of glucose metabolism. Because we are unable to retrieve information about patient location or medications from the databases, the magnitude of these potential overestimates is uncertain.

In summary, between about 10% to 20% of patients with laboratory data suggestive of diabetes may be unrecognized. Further research is necessary to determine if automated feedback of all laboratory results to the primary care provider, or other quality improvement interventions, can alleviate this problem.

Take-Home Points

- Unrecognized abnormal results from laboratory tests may be an important source of errors in the outpatient setting.
- We estimated the prevalence of unrecognized diabetes in a large MCO by using laboratory and administrative databases and selected chart review.
- Somewhere between 9% and 18% of patients with markedly abnormal glucose (i.e., plasma glucose ≥ 200 mg/dL or hemoglobin A_{1c} $\geq 7\%$) probably have unrecognized diabetes.
- The positive predictive value of the administrative data in identifying diabetes by ICD-9 codes was 0.94.
- Quality improvement initiatives involving automated feedback of abnormal laboratory values may alleviate the problem, but this hypothesis remains untested.

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