Analysis of Guidelines for Screening Diabetes Mellitus in an Ambulatory Population

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OBJECTIVES: **To compare the case-finding ability of current national guidelines for screening diabetes mellitus and characterize factors that affect testing practices in an ambulatory population.**

PATIENTS AND METHODS: **In this retrospective analysis, we reviewed a database of 46,991 nondiabetic patients aged 20 years and older who were seen at a large Midwestern academic physician practice from January 1, 2005, through December 31, 2007. Patients were included in the sample if they were currently being treated by the physician group according to Wisconsin Collaborative for Healthcare Quality criteria. Pregnant patients, diabetic patients, and patients who died during the study years were excluded. The prevalence of patients who met the American Diabetes Association (ADA) and/or US Preventive Services Task Force (USPSTF) criteria for diabetes screening, percentage of these patients screened, and number of new diabetes diagnoses per guideline were evaluated. Screening rates were assessed by number of high-risk factors, primary care specialty, and insurance status.**

RESULTS: **A total of 33,823 (72.0%) of 46,991 patients met either the ADA or the USPSTF screening criteria, and 28,842 (85.3%) of the eligible patients were tested. More patients met the ADA criteria than the 2008 USPSTF criteria (30,790 [65.5%] vs 12,054 [25.6%]), and the 2008 USPSTF guidelines resulted in 460 fewer diagnoses of diabetes (33.1%). By single high-risk factor, prediabetes (15.8%) and polycystic ovarian syndrome (12.6%) produced the highest rates of diagnosis. The number of ADA high-risk factors predicted diabetes, with 6 (23%) of 26 patients with 6 risk factors diagnosed as having diabetes. Uninsured patients were tested significantly less often than insured patients (54.9% vs 85.4%).**

CONCLUSION: **Compared with the ADA recommendations, the new USPSTF guidelines result in a lower number of patients eligible for screening and decrease case finding significantly. The number and type of risk factors predict diabetes, and lack of health insurance decreases testing.**

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ADA = American Diabetes Association; CI = confidence interval; FPG = fasting plasma glucose; HbA_{1c} = hemoglobin A_{1c}; *ICD-9* = *International Classification of Diseases, Ninth Revision*; PCOS = polycystic ovarian syndrome; RG = random glucose; USPSTF = US Preventive Services Task Force; WCHQ = Wisconsin Collaborative for Healthcare Quality

Diabetes mellitus has reached epidemic proportions in the United States. National Health and Nutrition Examination Survey data from 2005-2006 determined that the prevalence of diabetes in an ambulatory sample aged 20 years and older was 12.9%.[1] An additional 29.5% had either impaired fasting plasma glucose (FPG) levels, impaired glucose tolerance, or both; therefore, 42.4% of the US population aged 20 years or older has some degree of dysglycemia.[1] These numbers represent an increase since 1999-2002, when the National Health and Nutrition Examination Survey reported that the diabetic prevalence was 9.3%.[2] This trend is expected to continue, with 48.3 million Americans expected to have diabetes by 2050, a 198% increase compared with 2005.[3]

The prevalence of undiagnosed diabetes mellitus is equally alarming, with approximately 40% of the US diabetic population not knowing about their disease.[1] In total, 5.1% of the US population aged 20 years and older has diabetes but is unaware of the diagnosis. These patients are of particular concern because patients without knowledge of their disease obviously cannot be treated and may sustain progressive end-organ compromise. Harris et al[4] discovered retinopathy in almost 21% of patients with newly diagnosed diabetes, indicating that the disease may have been active for 4 to 7 years before the actual diagnosis. In addition, recent UK Prospective Diabetes Study data confirmed the "legacy effect" in patients with type 2 diabetes, a finding that was originally demonstrated in patients with type 1 diabetes in the Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications study.[5] This phenomenon refers to the finding that a period of untreated hyperglycemia, such as what might be expected in a patient with undiagnosed diabetes, has lasting effects on cardiovascular morbidity and mortality even if blood glucose levels are later appropriately controlled.[6,7] Thus, a more timely diagnosis may reduce these complications by creating an opportunity for early intervention and optimization of glycemic control.

Why the prevalence of undiagnosed diabetes remains high is unclear because screening guidelines have been in

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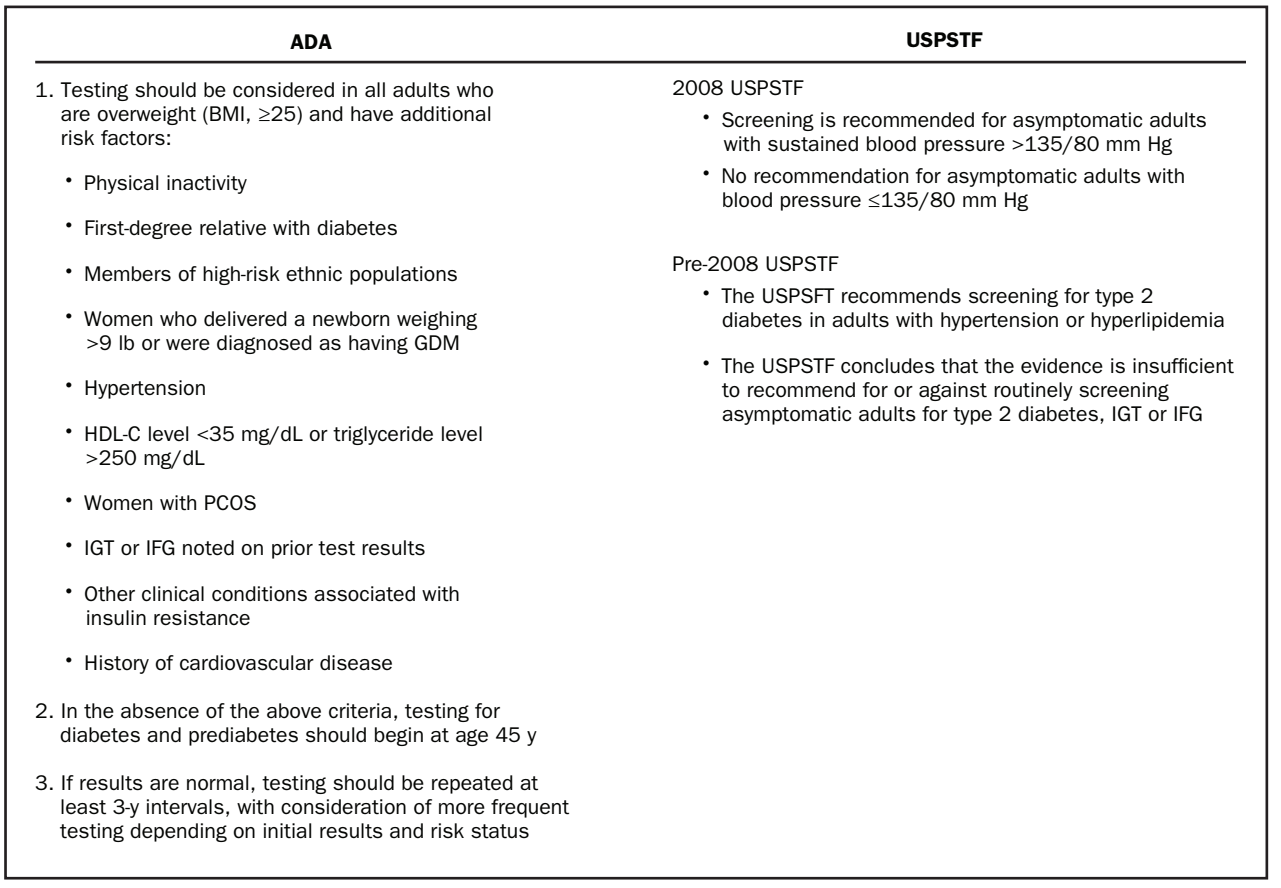

FIGURE 1. Criteria to screen for diabetes mellitus: American Diabetes Association (ADA) and/or US Preventive Services Task Force (USPSTF). BMI = body mass index; GDM = gestational diabetes mellitus; HDL-C = high-density lipoprotein cholesterol; IFG = impaired fasting glucose; IGT = impaired glucose tolerance; PCOS = polycystic ovarian syndrome. Adapted from the ADA[9] and the USPSTF,[10,11] with permission.

place for more than a decade. Since 1997, the American Diabetes Association (ADA) has recommended diabetes screening for patients 45 years and older, as well as in younger patients with high-risk factors (Figure 1).[8,9] The US Preventive Services Task Force (USPSTF) has consistently recommended diabetes screening for patients with hypertension and hyperlipidemia since the *Guide to Clinical Preventive Services, Third Edition*,[10] was published in series beginning in 2000. However, with the USPSTF 2008 update, hyperlipidemia was deleted as a criterion and diabetes screening was advised only for patients with blood pressure greater than 135/80 mm Hg (Figure 1).[10,11] These guidelines are based on evidence-based review of the literature (ADA and USPSTF) and expert opinion (ADA).

The failure of available guidelines to effectively reduce the number of patients with undiagnosed diabetes may be due to factors such as patients not presenting for care or physicians failing to screen. However, whether the guidelines themselves are targeting the correct at-risk population to maximize diabetes case finding is unknown. Despite extensive publication and commentary of the 2 primary guidelines (ADA and USPSTF),[12] it remains unclear how diabetes screening guidelines affect case finding in ambulatory practice. To our knowledge, there have been no systematic comparisons of the testing practices and case-finding ability of the ADA and USPSTF recommendations.

The primary objective of this study was to determine the diabetes case-finding ability of the ADA and USPSTF criteria when applied to clinical practice. In addition, we investigated whether patients with more ADA-designated high-risk factors were more likely to be tested, what risk factor was most predictive of a diabetes diagnosis, and whether a screening difference existed on the basis of primary care specialty or presence of health care insurance.

PATIENTS AND METHODS

We retrospectively analyzed diabetes screening practices in a large Midwestern academic physician group for the 3-year

period from January 1, 2005, through December 31, 2007. The University of Wisconsin, Madison Institutional Review Board approved the study and granted a waiver of consent for the Health Insurance Portability and Accountability Act. Patients' clinical, laboratory, encounter, and demographic data were obtained from the electronic health record of a large Midwestern academic physician group practice. These data include patient health care records, billing and payer information, and physician- and clinic-specific data generated from services rendered by physicians. Patients were included if they had had most of their visits at a clinic owned and operated by the physician group. These clinics serve patients in both referral and primary care practice. Since implementation in 2003, these clinics have contributed approximately 2 million patient, 48 million encounter, 47 million laboratory, 7 million pharmacy, and 434 million transaction records to the electronic health record.

Study Population

Patients were included in the sample during a specific year if they were "currently managed" by the physician group. Specifically, patients were required to have had at least 2 primary care office encounters in an outpatient, nonurgent setting, regardless of diagnosis code, with a primary care physician (internal medicine, gynecology, family practice, or pediatrics) in a primary care location in the prior 36 months, with at least 1 of those visits in the prior 24 months. This approach uses the previously established Wisconsin Collaborative for Healthcare Quality (WCHQ) definition of a "currently managed" population. This definition is the property of WCHQ and is used herein with their permission. The WCHQ is a diverse, voluntary, statewide partnership of health care institutions and organizations whose goal is to improve the quality of health care in Wisconsin.[13] These guidelines ensure that a patient who may have a single visit to a clinic but then seeks care permanently elsewhere is not included in screening measures based on the initial and only clinic visit.

Patients included were aged 20 years or older on January 1, 2005, and met the WCHQ criteria for being currently managed for each of the years 2005, 2006, and 2007. A 3-year window was chosen on the basis of the ADA recommendation for screening every 3 years. Data from the years 2003 and 2004 were used to determine prior diagnosis of diabetes, prediabetes, preexisting comorbidities, and pregnancy. Patients with any visit for pregnancy in the years 2003 to 2007 were excluded (eAppendix 1 online linked to this article) as were patients who died during the 3-year study period. Patients with 2 or more outpatient encounters with a diagnosis of diabetes mellitus in the years 2003-2004 were excluded (eAppendix 1).[14]

Demographic, clinical, and laboratory data were extracted for eligible patients. For all patients, age, sex, ethnicity, insurance status, and body mass index (calculated as weight in kilograms divided by height in meters squared) were extracted. Ethnicity was included because African American, Latino, Native American, Asian American, or Pacific Islander heritage is considered a risk factor for diabetes and is incorporated into the ADA guidelines for diabetes screening.[9] All evaluation and management outpatient encounter data, including date of service, physician specialty, and *International Classification of Diseases, Ninth Revision (ICD-9)*[15] codes were extracted. Diabetes screening tests were defined as FPG measurement, random glucose (RG) measurement, 2-hour glucose tolerance test, and hemoglobin A_{1c} (HbA_{1c}) measurement. The percentage of patients undergoing at least 1 test in the 3-year study period was recorded, with 74.3% having 1 or more RG measurements, 9.1% having 1 or more HbA_{1c} measurements, 0.8% having 1 or more FPG measurements, and 0.8% having 1 or more glucose tolerance tests, with some patients having more than 1 type of test performed. Although HbA_{1c} measurement was not an accepted diabetes screening test during the study years, it was included in our screening profile because it is known that physicians used HbA_{1c} measurement in this manner before its recent incorporation into guidelines.[16,17] Additional laboratory data extracted included levels of total cholesterol, high-density lipoprotein cholesterol, low-density lipoprotein cholesterol, and triglycerides.

Variable Definitions

Eight high-risk variables were defined on the basis of the ADA-designated risk factors for screening (Figure 1). These factors include age 45 years or older, high-risk ethnicity, hypertension, hypercholesterolemia, polycystic ovarian syndrome (PCOS), vascular disease (cardiovascular, peripheral vascular, or ischemic stroke), overweight (body mass index, ≥25), and history of prediabetes. Definitions for each high-risk variable were determined on the basis of a combination of 1 or more factors, including *ICD-9* code, laboratory data, and clinical information, with detailed criteria for each high-risk factor listed in eAppendix 2 (online linked to this article). When possible, validated definitions from Grundy et al,[18] Elixhauser et al,[19] Chronic Condition Warehouse,[20] Segars and Lea,[21] Hebert et al,[14] Goldstein,[22] and Tirschwell and Longstreth[23] were used to determine *ICD-9* codes. Two diagnosis codes on 2 separate occasions within 2 years were required to determine the presence of a high-risk factor. New cases of diabetes were determined by the presence of 2 validated *ICD-9* codes on 2 separate occasions within the 3-year study.[14]

The population that met the ADA and USPSTF screening criteria was determined on the basis of the defined high-

TABLE 1. **Baseline Patient Characteristics**

Characteristics	No. (%) of patients[a] (N=46,991)
Demographics, insurance, and visits	
Eligible for screening[b]	33,823 (72.0)
Female	27,921 (59.4)
Insurance	46,758 (99.5)
No. of primary care visits (mean [SD])[c]	46,991 (7.2 [5.0])
No. of specialty care visits (mean [SD])[c]	46,991 (3.9 [5.8])
Total No. of visits (mean [SD])[c]	46,991 (11.1 [8.8])
High-risk factors[d]	
Age ≥45 y	25,761 (54.8)
High-risk ethnic group	2089 (4.4)
Hypertension	12,054 (25.6)
Hypercholesterolemia	23,329 (49.6)
Polycystic ovarian syndrome	183 (0.4)
Prediabetes	165 (0.4)
Vascular disease	2589 (5.5)
Overweight	24,490 (52.1)
No. of high-risk factors[e]	
0	7751 (16.5)
1	11,169 (23.8)
2	11,639 (24.8)
3	10,396 (22.1)
4	5181 (11.0)
5	829 (1.8)
6	26 (0.06)
7	0 (0)
8	0 (0)
Patients meeting screening criteria	
Any criteria	33,823 (72.0)
ADA	30,790 (65.5)
≥45 y	25,761 (54.8)
<45 y and risk factors[f]	5029 (10.7)
Pre-2008 USPSTF	27,235 (58.0)
2008 USPSTF	12,054 (25.6)
Primary care specialty[g]	
Internal medicine	17,448 (37.1)
Family practice	26,695 (56.8)
Gynecology (nonobstetrics)	2719 (5.8)
Pediatrics	127 (0.3)

[a] ADA = American Diabetes Association; USPSTF = US Preventive Services Task Force.

[b] Includes patients eligible for screening under at least 1 screening guideline: ADA, pre-2008 USPSTF, and/or 2008 USPSTF.

[c] No. of primary care, specialty, and total visits is the mean No. of visits per patient from January 1, 2005, through December 31, 2007.

[d] High-risk factors generated from ADA screening criteria, as defined in eAppendix 2 (online linked to this article), are as follows: high-risk age, age ≥45 y; high-risk ethnicity, African American, Latino, Native American, Asian American, or Pacific Islander; hypertension, hypertension by criteria of Elixhauser et al[19]; cholesterol, hyperlipidemia, or hypertriglyceridemia per criteria of Segars and Lea,[21] high-density lipoprotein or triglycerides per ADA criteria,[9] or low-density lipoprotein level of 160 mg/dL or higher[18]; polycystic ovarian syndrome, by diagnosis code; prediabetes, impaired fasting glucose level, impaired glucose tolerance, subclinical diabetes, or gestational diabetes by diagnosis code; cardiovascular disease, including ischemic heart disease by Chronic Condition Data Warehouse criteria,[20] ischemic stroke by criteria of Goldstein[22] or Tirschwell and Longstreth,[23] and peripheral vascular disease by criteria of Elixhauser et al[19]; overweight, body mass index of 25 or higher or overweight or obese per criteria of Elixhauser et al.[19] No high-risk criteria established for the ADA risk factors of physical activity, first-degree relative with diabetes, and other clinical conditions associated with insulin resistance.

[e] No individual had 7 or 8 high-risk factors.

[f] Indicates patients <45 y who met the ADA screening criteria by having the risk factor overweight and ≥1 other high-risk factor besides age ≥45 y.

[g] Primary care specialty determined for each patient by specialty in which most or all of their primary care visits occurred.

risk factors. For ADA criteria, this included any patient 45 years or older or any overweight patient younger than 45 years with at least 1 additional high-risk factor. Eligibility for screening by USPSTF criteria was determined in 2 ways. First, screening practices were determined on the basis of the third edition of the USPSTF recommendations (pre-2008 USPSTF) to screen all hyperlipidemic and hypertensive patients because these guidelines were in place between the study years 2005 and 2007.[10] Second, the results of using hypertension alone as a criterion to screen were determined to estimate how the updated 2008 USPSTF guideline may be expected to perform if applied to this population.[11] The number of patients who met each screening criterion, the percentage of eligible patients screened, and the case-finding ability of diagnostic testing (number of new cases divided by number of eligible patients screened) were determined. The diabetes case-finding ability by individual risk factor and the number of high-risk factors were determined. Primary care specialty was defined as the specialty in which most or all of the patient's primary care visits occurred during the 3-year period. Screening adherence was evaluated on the basis of primary care specialty and presence or absence of insurance.

Statistical Analyses

Categorical variables were summarized using percentages. Continuous variables were summarized using means and SDs. Descriptive variables were presented overall and separately for each diabetes screening guideline. We conducted χ^2 tests for 2-way contingency tables comparing diabetes screening and diagnosis by insurance status and physician specialty, with the results presented as P values. $P \leq .05$ was considered statistically significant. To compare the proportion of patients screened, the proportion of conditions diagnosed, or the proportion of patients with diagnoses missed by different screening guidelines, 95% confidence intervals (CIs) were calculated using bootstrap techniques to replicate observations 1000 times.

RESULTS

A total of 51,034 patients met the inclusion criteria. Of these, 183 (0.4%) were excluded because of pregnancy, 982 (1.9%) because of death, and 3083 (6.0%) because of prior diagnosis of diabetes (note that some individuals met more than 1 of these criteria). Of the remaining 46,991 patients, 27,921 (59.4%) were female and 46,758 (99.5%) were insured. Of those 233 patients without insurance, 146 (62.7%) were younger than 45 years, and 124 (53.2%) were male. The mean ± SD number of visits to a primary care physician was 7.2±5.0 per person during the 3-year period of 2005-2007 (Table 1).

TABLE 2. **Comparison of Diabetes Screening Guidelines**[a]

Guidelines	No. eligible for screening[b]	No. (%; 95% CI) screened[c]	No. (%; 95% CI) diagnosed as having diabetes[d]	No. (%; 95% CI) of diagnoses missed per guideline[e]
Any criteria	33,823	28,842 (85.3; 84.9-85.6)	1390 (4.8; 4.6-5.1)	0 (0)
ADA[9]	30,790	26,597 (86.4; 86.0-86.8)	1329 (5.0; 4.7-5.3)	61 (4.4; 3.3-5.5)
≥45 y	25,761	22,440 (87.1; 86.7-87.5)	1134 (5.1; 4.8-5.3)	
<45 y and risk factors[f]	5029	4157 (82.7; 81.6-83.7)	195 (4.7; 4.1-5.3)	
Pre-2008 USPSTF[10]	27,235	24,221 (88.9; 88.6-89.3)	1293 (5.3; 5.0-5.6)	97 (7.0; 5.7-8.3)
2008 USPSTF[11]	12,054	11,333 (94.0; 93.6-94.4)	869 (7.7; 7.2-8.1)	521 (37.5; 35.0-40.0)

[a] ADA = American Diabetes Association; CI = confidence interval; USPSTF = US Preventive Services Task Force.
[b] Of a total of 46,991.
[c] Of those eligible.
[d] Of those eligible and screened.
[e] Indicates percentage of total diagnoses (1390 patients) that were missed by respective screening tests as applied in clinical practice in this database.
[f] Indicates patients <45 y who met the ADA screening criteria by being overweight and had ≥1 other high-risk factor besides high-risk age (high-risk ethnicity, hypertension, cholesterol, polycystic ovarian syndrome, prediabetes, or cardiovascular disease).

A total of 33,823 patients (72.0%) met at least 1 of the 3 screening criteria: ADA, pre-2008 USPSTF, or 2008 USPSTF. More patients met the ADA criteria (30,790 [65.5%]) than either the pre-2008 USPSTF (27,235 [58.0%]) or 2008 USPSTF (12,054 [25.6%]) criteria. Only 7751 patients (16.5%) had no high-risk factors. The most common high-risk factor was age 45 years or older (25,761 [54.8%]) followed by overweight (24,490 [52.1%]). Family practice (26,695 [56.8%]) was the most common primary care specialty (Table 1).

ADA and USPSTF Screening Criteria

In total, 30,790 patients met the ADA screening criteria, and 26,597 (86.4%; 95% CI, 86.0%-86.6%) of those eligible had 1 or more glucose tests performed (Table 2). Of those eligible and tested, 1329 patients (5.0%; 95% CI, 4.7%-5.3%) were diagnosed as having diabetes. Of patients who met the ADA guidelines, those with criteria to screen by age alone (≥45 years) were more likely to be tested than those younger than 45 years; those younger than 45 years qualified for screening on the basis of being overweight and having at least 1 additional high-risk factor (22,440 [87.1%] of 25,761 vs 4157 [82.7%] of 5029; 95% CI, 86.7%-87.5% and 81.6%-83.7%, respectively; $P<.001$).

A total of 27,235 patients met pre-2008 USPSTF criteria because of hypertension and/or hypercholesterolemia, and 24,221 (88.9%; 95% CI, 88.6%-89.3%) were screened. Of those who met the criteria and were screened, 1293 (5.3%; 95% CI, 5.0%-5.6%) were assigned a new diagnosis of diabetes. When patients with hypercholesterolemia were deleted to determine 2008 USPSTF eligibility (which is based on hypertension alone), only 12,054 patients met the criteria for screening, a reduction in 15,181 patients. Of the 2008 USPSTF patients, 11,333 (94.0%; 95% CI, 93.6%-94.4%) of 12,054 eligible patients were screened, with 869 (7.7%; 95% CI, 7.2%-8.1%) of those being diagnosed as having diabetes.

Of those 33,823 patients eligible for screening by any criteria, 28,842 (85.3%; 95% CI, 84.9%-85.6%) had at least 1 glucose test performed (Table 2). By individual screening criteria, a higher percentage of patients eligible and tested by 2008 USPSTF criteria were diagnosed as having diabetes compared with pre-2008 USPSTF and ADA criteria, respectively (7.7% vs 5.3% vs 5.0%; 95% CIs, 7.2%-8.1%, 5.0%-5.6%, and 4.7%-5.3%, respectively). However, the corresponding total number of patients diagnosed as having diabetes was lowest with the 2008 USPSTF criteria compared with the pre-2008 USPSTF and ADA criteria, respectively (869 vs 1293 vs 1329) because of the lower absolute numbers of patients eligible for screening under the 2008 USPSTF guideline.

In total, 1390 (4.8%; 95% CI, 4.6%-5.1%) of 28,842 patients eligible and tested by any criteria were diagnosed as having diabetes (Table 2). By individual guideline, when applied to clinical practice, the ADA screening criteria missed the fewest of these 1390 diagnoses, missing 61 patients (4.4%; 95% CI, 3.3%-5.5%), followed by 97 (7.0%; 95% CI, 5.7%-8.3%) missed with pre-2008 USPSTF. The 2008 USPSTF was significantly worse than either, missing 521 (37.5%; 95% CI, 35.0%-40.0%) of 1390 when applied to the study population. Of the 2 current screening guidelines, the 2008 USPSTF guidelines resulted in 460 fewer diagnoses of diabetes (33.1%) when compared with the case-finding ability of ADA criteria.

Number of Risk Factors, Primary Care Specialty, and Insurance Status

Patients most likely to be tested had prediabetes (100% of 164 patients), vascular disease (2427 [94.3%] of 2574 patients), and hypertension (11,333 [94.0%] of 12,054 patients) (Table 3). The high-risk factors associated with the highest rate of new diabetes diagnoses during the 3-year study period were prediabetes (26 [15.8%] of 164 patients), PCOS (17 [12.6%] of 135 patients), and vascular

TABLE 3. **Screening and Diagnosis by Risk Factor, Number of Risk Factors, Insurance, and Primary Care Specialty**

	No. eligible for screening[a]	No. (%) screened[b]	No. (%) diagnosed as having diabetes[c]
High-risk factors[d]			
Age ≥45 y	25,761	22,440 (87.1)	1134 (5.0)
High-risk ethnic group	1645	1357 (82.5)	112 (8.2)
Hypertension	12,054	11,333 (94.0)	869 (7.7)
Hypercholesterolemia	23,329	20,748 (88.9)	1102 (5.3)
Polycystic ovarian syndrome	152	135 (88.8)	17 (12.6)
Prediabetes	164	164 (100)	26 (15.8)
Vascular disease	2574	2427 (94.3)	243 (10.0)
Overweight	19,557	17,429 (89.1)	975 (5.6)
No. of high-risk factors[e]			
1	5759	3858 (67.0)	60 (1.6)
2	11,632	9508 (81.7)	264 (2.8)
3	10,396	9607 (92.4)	505 (5.3)
4	5181	5033 (97.1)	436 (8.7)
5	829	810 (97.7)	119 (14.7)
6	26	26 (100)	6 (23.1)
Insurance status			
Insurance	33,690	28,769 (85.4)	1380 (4.8)
No insurance	133	73 (54.9)	10 (13.7)
Primary care specialty[f]			
Internal medicine	14,239	12,914 (90.7)	606 (4.7)
Family practice	18,135	14,882 (82.1)	777 (5.2)
Gynecology (nonobstetrics)	1424	1035 (72.7)	7 (0.7)
Pediatrics	24	11 (45.8)	0 (0)

[a] A total of 33,823 were eligible for screening by any criteria.
[b] Of those eligible by any criteria.
[c] Of those eligible by any criteria and screened.
[d] High-risk factors generated from American Diabetes Association screening criteria, as defined in eAppendix 2 (online linked to this article).
[e] No individual had 7 or 8 high-risk factors.
[f] Primary care specialty determined for each patient by specialty in which most or all of their primary care visits occurred.

disease (243 [10.0%] of 2427 patients). Age 45 years or older (1134 [5.0%] of 22,440 patients) and hypercholesterolemia (1102 [5.3%] of 20,748 patients) produced the lowest rate of new diagnosis. The number of high-risk factors was strongly correlated with both screening and case-finding ability, with all 26 patients with 6 high-risk factors screened, and 6 (23%) of 26 diagnosed as having diabetes (Table 3 and Figure 2).

Patients without insurance were less likely to be tested with any glucose screening measurement compared with insured patients. In total, 73 (54.9%) of 133 eligible uninsured patients vs 28,769 (85.4%) of 33,690 insured patients were screened ($P<.001$). However, 10 (14%) of 73 uninsured patients vs 1380 (4.8%) of 28,769 insured patients were diagnosed as having diabetes, demonstrating a higher percentage of new cases of diabetes in the uninsured ($P=.002$). Eligible patients seen by internal medicine physicians were tested most often (12,914 [90.6%] of 14,239 patients) followed by family practice physicians (14,882 [82.1%] of 18,135 patients) and gynecologists (1035 [72.7%] of 1424 patients) ($P<.001$) (Table 3).

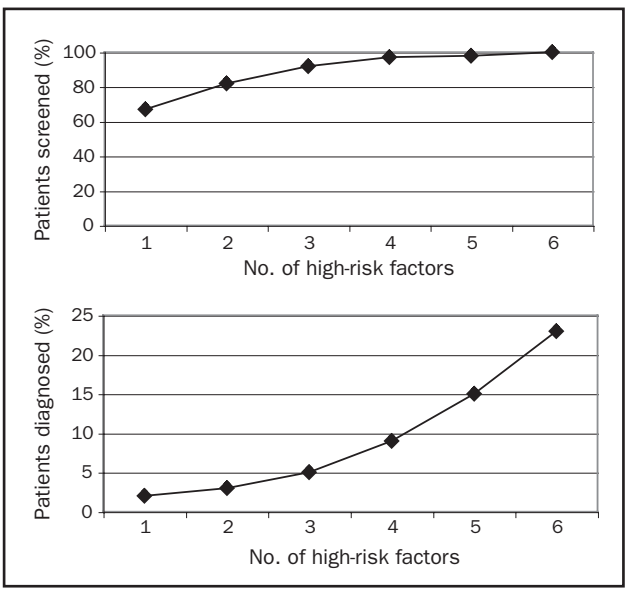

FIGURE 2. Percentage of patients screened for and diagnosed as having diabetes mellitus by number of high-risk factors. Patients were eligible for screening by either American Diabetes Association and/or US Preventive Services Task Force criteria.

DISCUSSION

This study represents a comprehensive evaluation of diabetes screening guidelines and practices in a large, ambulatory cohort. The ADA criteria identified more patients eligible for screening than either USPSTF standard, with the new 2008 USPSTF criteria recommending screening for a significantly smaller number of patients than either the pre-2008 USPSTF or ADA criteria. Most importantly, when the 2 current guidelines were applied to clinical practice, the decrease in the number of patients eligible for screening based on the new 2008 USPSTF criteria resulted in a significant reduction in diabetes case finding compared with the ADA criteria. On the basis of US Census data from 2005-2007, the prevalence of undiagnosed diabetes, and the performance of 2008 USPSTF guideline in the current study, nationwide use of the new USPSTF guideline alone would result in 3,650,390 fewer diabetes diagnoses in adults aged 20 years and older during the 3-year study period compared with the ADA guidelines.[1,24] This finding is of concern because many primary care physicians view USPSTF recommendations as standard of care and therefore may miss many cases of diabetes in their practice. Indeed, the USPSTF identifies itself as the "gold standard for clinical preventive services."[25]

Despite significantly better performance in clinical practice for diabetes case-finding ability, when compared with the 2008 USPSTF recommendations, the ADA criteria also failed to recommend screening for a subset of approximately 3000 patients who met at least 1 of the 2 USPSTF criteria. The specific patients missed by the ADA guideline were nonobese patients younger than 45 years with hypertension (pre-2008 and 2008 USPSTF) or hyperlipidemia (pre-2008 only). Patients younger than 45 years who met the ADA criteria for screening were significantly less likely to be tested than those 45 years and older. These high-risk, younger patients on average will have longer glycemic exposure during their lifetime because of their younger age and therefore should be an intense focus of future screening efforts.

A potential argument in favor of the new 2008 USPSTF guidelines could be the higher number of cases per number screened because 7.7% of patients screened under 2008 USPSTF standards were given a new diagnosis of diabetes, whereas only 5.0% of those screened under ADA criteria were diagnosed as having diabetes. However, the 7.7% figure is based on a much smaller number of eligible patients to begin with (12,054 vs 30,790), resulting in a significantly lower number of cases found compared with the ADA criteria. In addition, 5.0% is a high rate when compared with other well-accepted (and more costly) screening tests, such as mammography, which may produce fewer than 1 new diagnosis per 100 patients screened.[26]

When individual risk factors were evaluated, certain ADA high-risk factors were found to have particularly high case-finding ability; in particular, 15.8% of those with prediabetes and 12.6% of patients with PCOS were diagnosed as having diabetes during the study period. Patients with these less common but high-risk factors should be targeted for screening in clinical practice. Patients with multiple high-risk factors also present a screening priority because the amount of screening increases in a nonlinear manner, particularly with 4 or more high-risk factors.

Most of our patients eligible for screening by any criteria had been tested with at least 1 glucose screening measurement, although 15% of patients who met any screening guideline were not tested. The current study also revealed that screening practices were unequal across primary care subspecialties or by insurance status. Of patients who met the screening criteria, those seen most frequently by a gynecologist were less likely to have a diabetes screening test performed. This is worth noting because nonpregnant women of all ages seek primary care with gynecologists and should have access to the same preventive services as those in other primary care practices. In addition, this database was largely an insured population (99.5%) because of strict adherence to the WCHQ criteria mandating multiple physician visits, which almost certainly increased the frequency of screening found in this study compared with what could be expected with a larger uninsured population. However, even with the small number of uninsured patients studied, a worrisome trend in screening frequency was observed. Uninsured patients who met any screening criteria were tested significantly less, even among those patients who had clinic visits. Uninsured patients who do not come to the clinic were not captured in this study but almost certainly fare worse and remain a vulnerable population that should be targeted for public health outreach in the area of diabetes screening.[27]

The strengths of the current study are the large population size and the use and availability of standardized criteria to establish an accurate, comprehensive, and reproducible population. Acknowledging that every retrospective study has inherent limitations, we chose at every opportunity the most strict definition for inclusion criteria or risk factor definition. For example, we used strict WCHQ criteria for our sample definition even though it is likely that many patients seen only once (or not at all) in our clinics were still "clinic patients" and would be far less likely to be screened because of their infrequent visits. However, we could not distinguish an infrequent visitor from a patient who came to an eligible clinic once and then went elsewhere for care and was potentially screened, so we chose not to include these patients. Likewise, we used conservative criteria and determined that a patient had a risk factor only when the

risk factor appeared 2 or more times in their medical record or laboratory test results by predefined, standardized criteria when possible (eAppendix 2). Therefore, we were fairly confident that the risk factor was present and that the physician should be aware of that particular comorbidity. However, our database did not allow us to create ADA high-risk factors for family history, physical inactivity, and other conditions associated with insulin resistance; thus, we were not able to include every ADA risk factor, which could have resulted in more patients being eligible for ADA screening.

We included all glucose values in our database as screening data points, although some glucose values were measured for reasons other than screening, such as those measured incidentally as part of a basic chemistry panel. In addition, our database does not have mandatory entry for fasting status, so any unlabeled FPG test by default was classified as an RG test. These factors certainly resulted in underreporting of true FPG values and together help explain the apparent high incidence of RG values. However, our goal was to ensure that all possible attempts to screen were captured. Although the screening statistics in this report are a best-case scenario by design (despite the 15% rate of unscreened patients), we present a clear starting point for analyzing screening practices. However, because we could not always determine FPG status with absolute certainty and could not determine symptoms of hyperglycemia associated with an elevated RG level as required to diagnose diabetes,[9] the primary end point of our study, diagnosis of diabetes, was determined exclusively by validated diagnosis code criteria[14] and not by glucose laboratory data.

This study is a comprehensive review of diabetes screening guidelines and practices in a US subpopulation, including evaluation of case-finding ability and performance characteristics of the 2 current national screening guidelines. The most important finding of this analysis is that the new 2008 USPSTF criteria fail to include a large number of patients who would be eligible for screening by current ADA criteria, resulting in a concomitant reduction in discovery of new diabetes cases. Yet almost equally concerning is the discovery that our 2 current national screening guidelines (ADA and 2008 USPSTF) recommend screening for disparate populations. We believe that these findings together argue strongly for greater standardization of screening recommendations that also maximize diabetes case finding. With the epidemic of undiagnosed diabetes in the United States, we need to improve screening efforts, especially in light of the inexpensive, low-risk, and easily performed screening tests available.

Clearly, guidelines should be evidence based. Indeed, there is increasing concern that the integrity of guidelines in general may be in question, largely because any group or organization, regardless of bias, may issue a guideline and present it as standard of care.[28] However, the goal of a practice guideline is to help physicians make medical decisions on a daily basis. In most cases, the ideal evidence is unavailable or, at the very least, open to debate.[29] The USPSTF guidelines have historically been exclusively based on existing evidence, resulting in an "I Statement" of insufficient evidence in many of their clinical guidelines.[25] In the case of diabetes mellitus, the USPSTF acknowledged that the ideal clinical trial, randomizing screening-detected diabetes to treatment vs no treatment, would be unethical and therefore is unlikely to be performed.[30] Thus, if criteria for USPSTF guidelines remain bound to their current definition of evidence, the USPSTF may never be able to recommend comprehensive screening for a disease that is a national epidemic.

Fortunately, the USPSTF recently issued a statement addressing physician frustration with their guidelines, specifically the "I Statement," which plagues so many of their guidelines, including diabetes mellitus.[31] In this statement, they describe a newly adopted model for issuing recommendations when evidence is lacking. This model should certainly improve their guidelines, although it is unclear whether these changes will go far enough in providing comprehensive national recommendations to physicians who rely on them. Until revised USPSTF diabetes screening recommendations are available, we advocate following the evidence-based and expert opinion–driven ADA criteria because they will find more cases of diabetes when applied to clinical practice, as our study demonstrated. We also need to be vigilant about screening patients with multiple high-risk factors and individual risk factors that have high diagnostic predictive value, such as PCOS. Furthermore, we need to ensure that screening practices are robust across all ages and primary care specialties and for uninsured patients.

CONCLUSION

Multiple factors likely contribute to the high prevalence of undiagnosed diabetes. Although this study was not designed to investigate all these aspects, it showed that physicians who fail to screen eligible patients may play a role because not all our patients who should have been screened had a glucose test. In addition, lack of health insurance decreases testing, even in this uninsured patient population presenting for routine clinic visits.

This study also demonstrated that number and type of risk factors predict diabetes, and these findings should be considered in screening efforts. More importantly, suboptimal guidelines may ultimately contribute to maintaining the large undiagnosed diabetic population. Specifically

compared with ADA recommendations, the new USPSTF guidelines result in a lower number of patients eligible for screening and decrease case finding significantly. Health care professionals need to be aware of the blind spots in daily screening practices to effectively and promptly reduce the prevalence of undiagnosed diabetes in the the United States.

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