Clinical and Public Health Implications of 2019 Endocrine Society Guidelines for Diagnosis of Diabetes in Older Adults

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OBJECTIVE

Screening for diabetes is typically done using hemoglobin A_{1c} (HbA_{1c}) or fasting plasma glucose (FPG). The 2019 Endocrine Society guidelines recommend further testing using an oral glucose tolerance test (OGTT) in older adults with prediabetic HbA_{1c} or FPG. We evaluated the impact of this recommendation on diabetes prevalence, eligibility for glucose-lowering treatment, and estimated cost of implementation in a nationally representative sample.

RESEARCH DESIGN AND METHODS

We included 2,236 adults aged ≥65 years without known diabetes from the 2005–2016 National Health and Nutrition Examination Survey. Diabetes was defined using: 1) the Endocrine Society approach (HbA_{1c} ≥6.5%, FPG ≥126 mg/dL, or 2-h plasma glucose ≥200 mg/dL among those with HbA_{1c} 5.7–6.4% or FPG 100–125 mg/dL); and 2) a standard approach (HbA_{1c} ≥6.5% or FPG ≥126 mg/dL). Treatment eligibility was defined using HbA_{1c} cut points (≥7 to ≥9%). OGTT screening costs were estimated using Medicare fee schedules.

RESULTS

Diabetes prevalence was 15.7% (∼5.0 million) using the Endocrine Society's approach and 7.3% (∼2.3 million) using the standard approach. Treatment eligibility ranged from 5.4 to 0.06% and 11.8–1.3% for diabetes cases identified through the Endocrine Society or standard approach, respectively. By definition, diabetes identified exclusively through the Endocrine Society approach had HbA_{1c} <6.5% and would not be recommended for glucose-lowering treatment. Screening all older adults with prediabetic HbA_{1c}/FPG (∼18.3 million) with OGTT could cost between $737 million and $1.7 billion.

CONCLUSIONS

Adopting the 2019 Endocrine Society guidelines would substantially increase the number of older adults classified as having diabetes, require significant financial resources, but likely offer limited benefits.

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Age is one of the most important risk factors for type 2 diabetes. The prevalence of type 2 diabetes and prediabetes is highest in older age and the aging of the U.S. population suggests that diabetes will continue to be a major public health challenge in the coming years (1–3). There is growing attention to the unique clinical issues related to screening, diagnosing, and managing diabetes in the older adult population (4).

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In clinical practice, the usual approach to screening and diagnosis of diabetes in older adults is based on hemoglobin A_{1c} (HbA_{1c}) and/or fasting plasma glucose (FPG) testing ("standard diagnostic approach"). In clinical guidelines published in 2019 (5), the Endocrine Society endorsed the standard approach but also recommended administering a 2-h oral glucose tolerance test (OGTT) to adults aged ≥65 years with an HbA_{1c} and/or an FPG in the prediabetes range ("Endocrine Society diagnostic approach"). According to the Endocrine Society, this additional screening using the OGTT is important to avoid under-diagnosis, as "…many [older adults] affected with diabetes…are not diagnosed unless an OGTT is performed" (5).

The population-level impact of the Endocrine Society's approach to diabetes diagnosis is unclear. To this end, we used nationally representative data to compare the percentage of older adults who would be classified as having diabetes based on the Endocrine Society's approach versus the standard diagnostic approach. We also examined the percentage of older adults who would be eligible for glucose-lowering medication based on different recommended HbA_{1c} targets. Finally, we assessed the potential financial cost of administering an OGTT to all eligible older adults in the population per the Endocrine Society's new recommendation.

RESEARCH DESIGN AND METHODS
Study Population
The National Health and Nutrition Examination Survey (NHANES) is an ongoing, nationally representative, cross-sectional study designed to assess population health in the U.S. During each survey cycle, a sample of individuals are selected from the U.S. noninstitutionalized, civilian population using a complex, stratified, multistage probability cluster sampling design. Data are collected from participants through in-home interviews and visits to a mobile examination center. More details about the NHANES are available elsewhere (6). Study protocols were approved by National Center for Health Statistics institutional review board and participants provided written informed consent.

In this study, we pooled data from all NHANES survey cycles for which OGTTs were administered to study participants (2005–2016). We included participants in our analysis if they were aged 65 years or older, had no history of diagnosed diabetes, attended the fasting morning examination, and had data for all three measures of glycemia (HbA_{1c}, FPG, and 2-h plasma glucose [2-h PG]) available. These criteria yielded a final analytic sample of 2,236 participants.

Measurement of Glycemia
HbA_{1c} was measured using high-performance liquid chromatography methods (7). Plasma glucose was measured using the hexokinase method in fasting and 2-h post 75-g glucose load blood samples. To account for changes in laboratory methods over time, we calibrated plasma glucose using regression equations recommended in the National Center for Health Statistics analytic guidelines (8) and calibrated HbA_{1c} using an equipercentile equating approach (9).

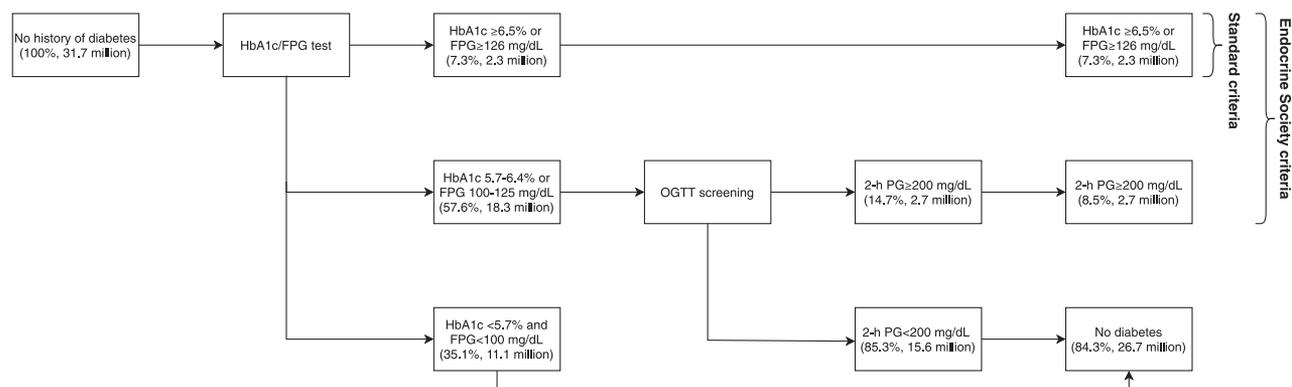### Approaches to Diabetes Diagnosis
We compared two approaches to identifying cases of diabetes in older adults (Fig. 1). The first was a standard approach, which defined diabetes as having a single elevated HbA_{1c} (≥6.5% [48 mmol/mol]) or single elevated FPG (≥126 mg/dL). The second was the Endocrine Society's diagnostic approach, which defined diabetes as an HbA_{1c} ≥6.5% (48 mmol/mol), FPG ≥126 mg/dL, or an elevated 2-h PG (≥200 mg/dL) among individuals who had prediabetic HbA_{1c} (5.7–6.4% [39–46 mmol/mol]) or FPG (100–125 mg/dL).

Sociodemographic and Risk Factor Measures
Computer-assisted interviews were conducted to collect information on participants' age, sex, race/ethnicity, education, household income, family history of diabetes, history of prediabetes, smoking status, and history of cardiovascular disease. Health information was also collected during physical examinations. Obesity was defined as BMI ≥30 kg/m^2 (10), abdominal obesity was defined as waist circumference ≥88 cm for women and ≥102 cm for men (11), hypertension was defined as mean blood pressure ≥140/90 mmHg or current use of blood pressure–lowering medication (12), high cholesterol was defined as total cholesterol ≥240 mg/dL or use of cholesterol-lowering medication (13), and microalbuminuria was defined as albumin/creatinine ratio ≥30 mg/g (14).

Statistical Analyses
We estimated the percentage of older adults in the U.S. that would be classified

Figure 1—Flow chart of diabetes status classification among U.S. adults aged 65 years and older with no prior diagnosis by different diagnostic approaches, NHANES 2005–2016. Participants meeting diabetes by the Endocrine Society criteria had HbA_{1c} ≥6.5% (48 mmol/mol), FPG ≥126 mg/dL, or 2-h PG ≥200 with prediabetic HbA_{1c} or FPG. Participants meeting diabetes by the standard criteria had HbA_{1c} ≥6.5% (48 mmol/mol) or FPG ≥126 mg/dL.

Table 1—Percentage of U.S. adults aged 65 years and older (95% CI) with no prior diagnosis who would be classified as having diabetes by different diagnostic approaches, NHANES 2005–2016

	Endocrine Society approach*			Standard approach†			Endocrine Society but not standard approach‡		
	Percentage	95% CI	P value§	Percentage	95% CI	P value§	Percentage	95% CI	P value§
Overall	15.7	13.9–17.7		7.3	6.0–8.7		8.5	7.1–10.0	
Age (years)									
65–74	12.8	10.8–15.1	0.00	6.8	5.3–8.6	0.27	6.0	4.6–7.8	0.00
≥75	20.2	17.3–23.5		8.0	6.4–10.0		12.2	9.9–15.0	
Sex									
Male	16.3	13.6–19.4	0.62	8.5	6.8–10.5	0.12	7.8	5.8–10.3	0.38
Female	15.3	13.0–18.0		6.3	4.7–8.5		9.0	7.4–10.8	
Race/ethnicity									
Non-Hispanic white	15.6	13.4–18.0	0.21	7.1	5.7–8.8	0.34	8.5	6.8–10.5	0.38
Mexican-American	21.8	16.0–28.8		9.5	5.5–15.8		12.3	8.3–17.9	
Non-Hispanic black	16.8	12.6–22.0		9.0	6.1–13.2		7.7	4.7–12.5	
Educational level									
Beyond high school	12.5	10.2–15.2	0.00	6.0	4.4–8.1	0.04	6.5	5.0–8.3	0.01
High school or lower	19.5	16.6–22.7		8.8	7.0–10.9		10.7	8.4–13.5	
Poverty/income ratio <130%									
No	14.5	12.3–16.9	0.00	6.7	5.2–8.5	0.04	7.8	6.2–9.7	0.01
Yes	23.5	19.0–28.5		10.5	7.5–14.4		13.0	9.3–17.9	
Family history of diabetes									
No	15.0	12.9–17.4	0.01	6.5	5.0–8.4	0.04	8.5	6.9–10.3	0.36
Yes	19.9	16.4–23.9		9.9	7.2–13.6		9.9	7.3–13.5	
Prior history of prediabetes									
No	12.8	11.0–14.8	0.00	5.3	4.2–6.6	0.00	7.5	6.1–9.2	0.05
Yes	31.2	23.4–40.2		18.8	12.7–26.9		12.4	7.7–19.3	
Smoking									
Never smoker	15.0	12.7–17.7	0.57	6.7	5.0–8.8	0.61	8.3	6.5–10.6	0.77
Former smoker	16.0	13.1–19.5		7.8	6.0–10.1		8.3	6.2–10.9	
Current smoker	18.2	13.4–24.3		8.2	5.0–12.9		10.0	6.3–15.6	
Obese									
No	12.3	10.3–14.6	0.00	4.5	3.6–5.6	0.00	7.8	6.2–9.9	0.22
Yes	23.3	19.4–27.8		13.4	10.3–17.2		10.0	7.5–13.1	
Abdominal obesity									
No	9.6	7.6–12.2	0.00	3.7	2.7–5.2	0.00	5.9	4.3–8.1	0.00
Yes	18.5	16.1–21.1		8.5	6.8–10.7		9.9	8.1–12.0	
Hypertension									
No	9.2	7.1–11.9	0.00	4.5	3.0–6.6	0.00	4.7	3.3–6.8	0.00
Yes	19.2	16.9–21.7		8.5	7.1–10.3		10.7	8.9–12.7	
High cholesterol									
No	14.5	12.0–17.3	0.13	7.5	5.9–9.5	0.64	6.9	5.4–8.9	0.02
Yes	17.1	14.8–19.6		7.0	5.5–8.9		10.1	8.0–12.5	
History of CVD									
No	14.7	12.7–16.8	0.03	6.8	5.5–8.3	0.17	7.9	6.5–9.6	0.11
Yes	19.1	15.5–23.3		8.8	6.3–12.3		10.2	7.7–13.5	
Microalbuminuria									
No	14.0	11.9–16.3	0.00	6.6	5.2–8.3	0.05	7.4	5.9–9.2	0.00
Yes	24.1	19.7–29.0		10.3	7.4–14.1		13.8	10.5–17.9	

CVD, cardiovascular disease. *Participants meeting diabetes by the Endocrine Society approach had $HbA_{1c} \geq 6.5\%$ (48 mmol/mol), FPG $\geq$126 mg/dL, or 2-h PG $\geq$200 with prediabetic HbA_{1c} or FPG. †Participants meeting diabetes by the standard approach had $HbA_{1c} \geq 6.5\%$ (48 mmol/mol) or FPG $\geq$126 mg/dL. ‡Participants meeting diabetes by only the Endocrine Society approach had 2-h PG $\geq$200 with prediabetic HbA_{1c} or FPG. §P values are from χ^2 tests.

as having diabetes according to the standard approach and Endocrine Society's diagnostic approach. We also estimated the percentage of the population that would be defined as "new" cases of diabetes identified exclusively through the additional OGTT screening recommended in the Endocrine Society guidelines. We computed these percentages in the overall population and across categories of participant characteristics. We used χ^2 tests to assess differences in prevalence across participant characteristics for each definition of diabetes.

Among adults classified as having diabetes, we determined the percentage that would be eligible for glucose-lowering medication based on their HbA1c. Major guidelines recommend different HbA_{1c} treatment targets in specific subpopulations (15,16), including older adults for

Table 2—Percentage of the population (95% CI) eligible for glucose-lowering medication treatment according to different HbA$_{1c}$ thresholds among persons meeting the 2019 Endocrine Society definition of diabetes for older adults and standard diagnostic criteria for diabetes, U.S. adults aged 65 years and older with no prior diagnosis of diabetes, NHANES 2005–2016

Treatment threshold	Diabetes by Endocrine Society criteria (n = 398)*		Diabetes by standard criteria (n = 188)†	
	Percentage	95% CI	Percentage	95% CI
HbA$_{1c}$ ≥7.0%	5.4	2.5–8.4	11.8	5.5–18.0
HbA$_{1c}$ ≥7.5%	3.3	0.9–5.7	7.1	2.0–12.3
HbA$_{1c}$ ≥8.0%	2.0	0.0–4.0	4.4	−0.0 to 8.8
HbA$_{1c}$ ≥8.5%	1.6	−0.3 to 3.5	3.4	−0.7 to 7.6
HbA$_{1c}$ ≥9.0%	0.6	−0.0 to 1.3	1.3	−0.1 to 2.8

*Participants meeting diabetes by the Endocrine Society criteria had HbA$_{1c}$ ≥6.5% (48 mmol/mol), FPG ≥126 mg/dL, or 2-h PG ≥200 with prediabetic HbA$_{1c}$ or FPG. †Participants meeting diabetes by the standard criteria had HbA$_{1c}$ ≥6.5% (48 mmol/mol) or FPG ≥126 mg/dL.

whom the targets range from <7.0 to <9.0% (53–75 mmol/mol). For instance, the Endocrine Society suggests a glycemic target between 7.5 and 8.5%, depending on patients' health status (5). Given this variability, we examined five different HbA$_{1c}$ thresholds: ≥7.0%, ≥7.5%, ≥8.0%, ≥8.5%, and ≥9.0% (≥53, ≥58, ≥64, ≥69, and ≥75 mmol/mol, respectively).

We estimated the potential additional financial cost associated with using OGTT to screen for undiagnosed diabetes among older adults with prediabetic levels of HbA$_{1c}$ or FPG. Adopting a health system perspective, we only considered the direct medical cost of an OGTT. We evaluated expenses for physician visits and laboratory tests, as these two make up the bulk of medical costs for OGTT screenings. We determined costs using Medicare fee schedules (17,18). We assumed that OGTT screenings would be performed as part of a general office visit for established patients and used the corresponding reimbursement rate for this service. However, because similar visits can be billed in different ways (19–21), we evaluated scenarios using a low, medium, and high office visit

billing code (Current Procedural Terminology codes 99212, 99213, and 99214, respectively). All costs were expressed in 2019 U.S. dollars.

Analyses were conducted using Stata 15.0 (StataCorp) and used the OGTT sample weights, making the results in this study representative of the civilian, noninstitutionalized U.S. population aged 65 years or older. A two-sided P value <0.05 was considered statistically significant.

RESULTS

Among older adults in the U.S. with no prior diagnosis of diabetes, 15.7% (~5.0 million) would be classified as having diabetes based on the Endocrine Society's diagnostic approach, compared with 7.3% (~2.3 million) based on the standard approach (Table 1 and Fig. 1). The Endocrine Society recommendation to use OGTT screening in older adults with prediabetes thus resulted in an additional 8.5% (~2.7 million) individuals being classified as having diabetes; these new cases were more common among those who were age 75 and older, less educated, and lower income.

Among older adults who met criteria for diabetes based on the Endocrine Society's approach, between 0.06 (~0.03 million) and 5.4% (~0.27 million) could be considered for glucose-lowering treatment, depending on the HbA1c threshold used to define eligibility (Table 2). In contrast, between 1.3 (~0.03 million) and 11.8% (~0.27 million) of those who met the standard criteria for diabetes would be eligible for glucose-lowering medication treatment based on differing levels of HbA$_{1c}$. By definition, older adults who met the Endocrine Society criteria but not the standard definition of diabetes had prediabetic levels of HbA$_{1c}$ (5.7–6.4% [39–46 mmol/mol]), making them ineligible for glucose-lowering treatment at all thresholds, as pharmacologic treatment for diabetes is not recommended in older adults with HbA$_{1c}$ <7% (<53 mmol/mol).

An estimated 57.6% (~18.3 million) of older adults in the US had prediabetic HbA$_{1c}$ or FPG and would be recommended for OGTT screening under the Endocrine Society's guidelines (Table 3 and Fig. 1). Testing all these individuals was estimated to cost between $737 million and $1.73 billion in 2019 U.S. dollars.

CONCLUSIONS

Recent guidelines issued by the Endocrine Society recommend administering an OGTT in all older adults with prediabetic HbA$_{1c}$ or FPG to identify additional cases of diabetes (2-h PG ≥200 mg/dL). Our analysis of data from NHANES showed that adopting this practice would more than double the number of older adults classified as having diabetes, from ~2.3 to ~5.0 million. However, these new cases would be ineligible for glucose-lowering medication under current guidelines. ndeed, the lowest agreed upon HbA$_{1c}$ treatment target for older adults in current diabetes guidelines is 7.0% (53 mmol/mol)

Table 3—Projected medical cost of recommended OGTT screenings in U.S. adults aged 65 years and older with no prior diagnosis of diabetes, 2019 dollars

Type of billing code used for visit	Cost of office visit	Cost of laboratory test	Total cost per OGTT	Total number eligible	Projected medical cost
Low	$25.95	$14.30	$40.25	~18.3 million	~$737 million
Medium	$51.90	$14.30	$66.29	~18.3 million	~$1.21 billion
High	$80.01	$14.30	$94.31	~18.3 million	~$1.73 billion

Projections assume that 2019 Endocrine Society guidelines recommendations are fully implemented (i.e., all older adults with prediabetic HbA$_{1c}$ or FPG are screened with an OGTT). The costs of low-, medium-, and high-cost visits are based on Current Procedural Terminology codes 99212, 99213, and 99214, respectively, and come from the 2019 Medicare physician fee schedule. Costs for an OGTT come from the 2019 Medicare clinical laboratory fee schedule.

(15). The individuals recommended for OGTT screening in the Endocrine Society guidelines would already be eligible for evidence-based lifestyle modification (22) on the basis of their prediabetic HbA_{1c} and/or FPG (i.e., regardless of their 2-h PG value) (5,23). Our results suggest that the recommendation to screen prediabetic older adults with an OGTT may offer little, if any, direct benefit.

On the other hand, there are plausible ways in which the OGTT recommendation may unintentionally harm older adults. First, it risks subjecting the 18.3 million older adults in the U.S. with prediabetic HbA1c or FPG to the burdensome process of fasting and receiving a 2-h glucose challenge test. OGTT testing may be especially onerous in older adults, given the high burden of comorbidities and frailty in this population (24,25). Second, our analysis found that screening eligible older adults with an OGTT could cost between $737 million and $1.73 billion. These estimates assume 100% screening implementation but nonetheless suggest that this approach (even if not fully adopted) would divert health care and financial resources away from strategies that may more effectively identify and treat high-risk patients. Third, expanding the definition of diabetes to individuals who are not eligible for pharmacological treatment may unnecessarily expose older adults to psychological and social distress that can accompany a diagnosis of diabetes (26). This is a particular concern for vulnerable populations such as those from low-socioeconomic backgrounds (26), who were disproportionately identified has having diabetes through OGTT testing in this study.

There is little evidence directly supporting the proposed OGTT screening strategy. The individuals identified by the application of OGTT as recommended by the Endocrine Society will have diabetes identified by 2-h PG criteria only. The prognosis associated with diabetes defined solely by 2-h PG is poorly characterized among older adults, and has not been assessed in the context of using HbA_{1c} as a diagnostic test for diabetes (27–33). Moreover, the clinical value of treating older adults with an isolated elevation in 2-h PG is unclear, as clinical trials of diabetes treatment have not specifically included older individuals based on OGTT criteria. The cost

effectiveness of early detection and treatment of diabetes using OGTT among older adults is also uncertain. For example, the simulation study cited by the Endocrine Society guidelines to support aggressive diabetes detection among older individuals included only middle-aged adults (34). The paucity of evidence raises further questions around whether a broad OGTT screening strategy is warranted for older adults.

The findings from this study must be considered in light of several limitations. First, our definitions of diabetes were based on single elevated test results of HbA_{1c}, FPG, or 2-h PG. In practice, diagnosis of diabetes would be confirmed with a second test (35,36). Moreover, while older adults with known diabetes were excluded, this information was self-reported. Second, our cost analysis involved several simplifying assumptions, including only focusing on two types of medical costs. However, the goal in this study was not to determine precisely the exact cost of OGTT screenings, but rather to provide a general idea of potential financial implications. Third, prevalence estimates for certain subgroups with limited sample size were imprecise and should be interpreted with caution.

Our study had several strengths. The NHANES is the only nationally representative sample of older adults in the U.S. with measures of HbA_{1c}, FPG, and 2-h PG. All measurements in this study were obtained in a rigorous and standardized fashion by trained personnel.

In conclusion, implementing additional OGTT screenings in prediabetic older adults as recommended by the Endocrine Society's guidelines would substantially increase the number of older adults in the U.S. classified as having diabetes. At the same time, the 2-h glucose test would offer limited information related to medication eligibility, as newly identified cases would, by definition, have HbA_{1c} levels below targets for pharmacotherapy. Moreover, administering the OGTT on a broad scale would be expensive and burdensome, particularly for older adults. Based on these findings, we caution that OGTT may not be a useful screening test in the general population of older adults who have HbA_{1c} and FPG levels below current thresholds for the diagnosis of diabetes.

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