



# HbA<sub>1c</sub> overtesting and overtreatment among US adults with controlled type 2 diabetes, 2001-13: observational population based study

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## ABSTRACT

### STUDY QUESTION

What is the extent and effect of excessive testing for glycated hemoglobin (HbA<sub>1c</sub>) among adults with controlled type 2 diabetes?

### METHODS

A retrospective analysis of data from a national administrative claims database included commercially insured individuals in the USA, 2001-13. Study patients were aged 18 years or older, had type 2 diabetes with stable glycemic control (two consecutive tests showing HbA<sub>1c</sub><7.0% within 24 months), did not use insulin, had no history of severe hypoglycemia or hyperglycemia, and were not pregnant. HbA<sub>1c</sub> testing frequency was measured within 24 months after the second (index) HbA<sub>1c</sub> test, and classified as guideline recommended ( $\leq 2$  times/year), frequent (3-4 times/year), and excessive ( $\geq 5$  times/year). Changes in treatment regimen were ascertained within three months of the index test.

### STUDY ANSWER AND LIMITATIONS

Of 31545 patients in the study cohort (mean age 58 years; mean index HbA<sub>1c</sub> 6.2%), HbA<sub>1c</sub> testing frequency was excessive in 6% and frequent in 55%. Despite good glycemic control at baseline, treatment was further intensified by addition of glucose lowering drugs or insulin in 8.4% of patients (comprising 13%, 9%, and 7% of those tested excessively, frequently,

and per guidelines, respectively;  $P < 0.001$ ). Compared with guideline recommended testing, excessive testing was associated with treatment intensification (odds ratio 1.35 (95% confidence interval 1.22 to 1.50)). Excessive testing rates remained unchanged in 2001-08, but fell significantly after 2009. The odds of excessive testing was 46% lower in 2011 than in 2001-02. The study population is not representative of all US patients with type 2 diabetes because it was restricted to commercially insured adults with stable and controlled diabetes not receiving insulin treatment. The study design did not capture the underuse of HbA<sub>1c</sub> testing.

### WHAT THIS STUDY ADDS

In this US cohort of adults with stable and controlled type 2 diabetes, more than 60% received too many HbA<sub>1c</sub> tests, a practice associated with potential overtreatment with hypoglycemic drugs. Excessive testing contributes to the growing problem of waste in healthcare and increased patient burden in diabetes management.

### FUNDING, COMPETING INTERESTS, DATA SHARING

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## Introduction

Regulatory bodies, both public and private, use metrics on glycated hemoglobin (HbA<sub>1c</sub>) to guide pay-for-performance reimbursement and public reporting in the care of patients with type 2 diabetes.<sup>1-3</sup> Current clinical practice guidelines recommend HbA<sub>1c</sub> of less than 6.5%, 7.0%, or 8.0%, depending on the agency and the individual patient's goals and clinical complexity.<sup>4-10</sup> Frequent HbA<sub>1c</sub> monitoring is often needed for patients with variable glycemic control, receiving intensive insulin treatment, or needing tightly regulated control (such as pregnant women). However, for patients who are meeting treatment goals, have stable glycemic control, and have had no complications of glucose lowering treatment such as hypoglycemia, current guidelines agree that HbA<sub>1c</sub> should be tested less frequently, once or twice annually.<sup>4-9</sup> Currently, guidelines do not prescribe minimum testing frequencies and implications of exceeding recommended frequencies are not discussed, probably because of a lack of evidence that excessive testing causes patient harm. Yet, among patients with stable and controlled disease, more frequent HbA<sub>1c</sub> testing might not benefit the patient, but

## WHAT IS ALREADY KNOWN ON THIS TOPIC

Professional societies and regulatory bodies recommend that glycated hemoglobin (HbA<sub>1c</sub>) is checked once or twice a year in non-pregnant adults with type 2 diabetes who have achieved and maintained glycemic control without use of insulin and without recent acute diabetes complications

Several studies have suggested a high prevalence of repeat HbA<sub>1c</sub> testing, contributing to redundancy and waste in healthcare

These studies were relatively small, did not differentiate among patients needing different degrees of glycemic monitoring and control, and did not assess the effect of excessive testing on treatment

## WHAT THIS STUDY ADDS

In a national US cohort of 31545 non-pregnant adults with type 2 diabetes, who did not use insulin and who achieved and maintained HbA<sub>1c</sub> levels of less than 7.0%, 6% of patients had five or more HbA<sub>1c</sub> tests over one year, and 55% had three or four tests over one year

Excessive testing increased the odds of diabetes treatment intensification despite normal HbA<sub>1c</sub> levels (odds ratio 1.35 (95% confidence interval 1.22 to 1.50)), compared with guideline recommended testing

Excessive testing is ineffective and inefficient, contributing to the growing problem of waste in healthcare and increasing patient burden in the management of type 2 diabetes

would contribute to their treatment burden, resource use, and healthcare costs. Potential effects on overtreatment and resultant hypoglycemia, however, are not known.

Several studies raised concerns about HbA<sub>1c</sub> testing frequency among patients with diabetes. A study of patients with newly diagnosed diabetes in the Veterans Affairs Administration (VA) found that during the year following a new diabetes diagnosis, 38% of patients were tested at least three times and 4.2% were tested at least five times.<sup>11</sup> Several other studies conducted in the United States, Europe, and Turkey similarly suggested a high prevalence of redundant HbA<sub>1c</sub> testing, but—like the VA study—did not differentiate across patients needing different degrees of glycemic monitoring.<sup>12-14</sup> Although most agree that testing five or more times per year is redundant (considering that HbA<sub>1c</sub> is a measure of average glycemia over three months), quarterly monitoring might be indicated in patients with newly diagnosed or pregnancy associated diabetes, rapidly changing HbA<sub>1c</sub> levels, treatment changes, insulin use, or history of hypoglycemia.<sup>11</sup> To strictly evaluate the magnitude of unequivocally inappropriate testing in the general US population, patients at low risk for deterioration of glycemic control and no indication for intensive monitoring should therefore be examined separately.

Moreover, excessive testing could prompt providers to overtreat, either by intensifying treatment despite glycemic targets that are still at goal, or by failure to de-escalate treatment with stable, albeit low HbA<sub>1c</sub> levels. Such overtreatment could lead to patient harm through hypoglycemia, increased cost of care, and other treatment side effects. While identifying these adverse health and economic outcomes was beyond the scope of this study, research into this important area is ongoing. In this work, we present a population level estimate of HbA<sub>1c</sub> testing frequencies and treatment consequences among commercially insured adults and Medicare Advantage beneficiaries with type 2 diabetes across the USA who have achieved and maintained glycemic control without use of insulin.

## Methods

### Dataset

We conducted a retrospective analysis of data from the Optum Labs Data Warehouse (OLDW), an administrative claims database of more than 86 million commercially insured and Medicare Advantage enrollees throughout the USA between 2001 and 2014.<sup>15</sup> OLDW includes individuals of all ages and races, and in all 50 US states, with greatest representation in the midwest and south US census regions.<sup>16</sup> The plan provides fully insured coverage for professional, facility, and outpatient prescription medication services. Medical claims include ICD-9-CM (international classification of diseases, 9th revision, clinical modification) diagnosis and procedure codes, Current Procedural Terminology (CPT) version 4 procedure codes, Healthcare Common Procedure Coding System procedure codes, site of service codes, and provider specialty codes. Laboratory data,

available for a subset of individuals based on data sharing agreements, includes test names, logical observation identifiers names and codes (LOINC), and test results.<sup>17</sup>

Study data were statistically deidentified and accessed according to the Health Insurance Portability and Accountability Act (HIPAA) 164.514 privacy rule. The Mayo Clinic Institutional Review Board exempted this study from approval as it represents research on pre-existing, deidentified data.

### Patient population

We identified all patients with diabetes mellitus, aged at least 18 years, who had an HbA<sub>1c</sub> laboratory test performed between 1 January 2001 and 31 December 2011. Patients with diabetes were identified on the basis of criteria from the Healthcare Effectiveness Data and Information Set.<sup>3</sup> We excluded patients with type 1 diabetes (ICD-9-CM codes 250.x1 and 250.x3), gestational diabetes (ICD-9-CM codes 648.0x, 648.8x), non-clinical diabetes (ICD-9-CM code 790.29), and secondary diabetes (ICD-9-CM codes 249.x). These conditions have different pathophysiologies and natural histories, and therefore different monitoring and treatment goals. ICD-9-CM codes from the top three diagnoses of any evaluation and management (E/M) encounter were queried to identify these criteria. Eligible patients had at least 24 months of continuous enrolment before and after the index HbA<sub>1c</sub> test.

To restrict the population to patients with controlled and stable disease, only patients with two consecutive HbA<sub>1c</sub> test readings below 7.0% within a 24 month period were included. The index test was the second HbA<sub>1c</sub> test; the first HbA<sub>1c</sub> test was required to establish stability of glycemic control. Thus, all patients included in the study had at least two HbA<sub>1c</sub> tests within 24 months. We excluded patients who were not subject to usual care and monitoring frequency.<sup>4-10</sup> Excluded individuals were those treated with insulin within 120 days before the index date, who were pregnant, or with a history of hypoglycemic and hyperglycemic acute diabetes complications as one of three diagnoses during an E/M encounter within 12 months before the index date. Such complications included diabetic ketoacidosis (ICD-9-CM codes 250.1x), hyperglycemic hyperosmolar state (250.2x), unspecified diabetic coma (250.3x), hypoglycemia (251.x and 250.8 according to the Ginde algorithm),<sup>18</sup> or poisoning by insulin or antidiabetic drugs (962.3). Patients entered the study cohort once, the first time they became eligible by having a second sequential HbA<sub>1c</sub> result less than 7.0%, and were followed prospectively for 24 months. All patients therefore had at least four years of uninterrupted enrollment, two years before and two years after the index test date.

We identified HbA<sub>1c</sub> studies using CPT-4 codes 83036 and 83037 in the claims files and LOINC codes 4548-4, 4549-2, 17856-6, 59261-8, 62388-4, and 4547-6 in the laboratory results file (web appendix 1J). Patients were stratified by baseline HbA<sub>1c</sub> measurements ( $\leq 5.6\%$ ; 5.7-6.4%; and 6.5-6.9%). These HbA<sub>1c</sub> thresholds were chosen to differentiate between very tight ( $\leq 5.6\%$ ), tight

(5.7-6.4%), and guideline recommended (6.5-6.9%) glycaemic control.

#### Patient involvement

No patients were involved in setting the research question or the outcome measures, nor were they involved in developing plans for design or implementation of the study. No patients were asked to advise on interpretation or writing up of results. There are no plans to disseminate the results of the research to study participants or the relevant patient community.

#### Primary outcome

The primary outcome was HbA<sub>1c</sub> testing frequency, measured as the mean number of tests per year obtained during the first 24 months following the index HbA<sub>1c</sub> test. We categorized testing frequency according to the most recent clinical practice guidelines (web appendix 2):

- Guideline recommended: up to two tests per year, or tests obtained six or more months apart
- Frequent: three to four tests per year, or tests obtained at least three but less than six months apart
- Excessive: at least five tests per year, or tests obtained less than three months apart.

#### Secondary outcome

We assessed changes to diabetes treatment regimen by comparing pharmacy claims 120 days after the index date with claims 120 days before the index date. Treatment intensification was defined as the increase in the number of glucose lowering drugs or addition of insulin, while treatment deintensification was defined as the discontinuation of at least one drug; none of the patients was using insulin at baseline. Drug changes that maintained the same number of substances used were classified as class switches, and assumed to be neither intensification nor deintensification.

#### Independent variables

To assess the influence of disease burden and clinical complexity, the Charlson comorbidity index for one calendar year before the index test date was derived from ICD-9-CM diagnoses included in administrative claims. The Charlson index is a widely used measure that weighs comorbid conditions by the strength of their association with one year mortality;<sup>19</sup> it has been previously validated for use in diabetes.<sup>20 21</sup> Year of the index HbA<sub>1c</sub> (2001-11) was recorded and presented as two year increments except for 2011. Demographics included age, sex, race or ethnic origin, and census region. Age and sex were obtained directly from enrolment data. We obtained information on race or ethnic origin by linking administrative claims to a third party dataset of demographic characteristics.

Baseline treatment regimens were identified from pharmacy claims issued within 120 days preceding the index test date. We grouped drugs into nine classes (web appendix 3). Drug combinations were considered as belonging to both classes. We used E/M CPT codes to

determine the number of face to face clinical encounters. The number and specialties of unique providers seen were measured for the 12 month period following the index HbA<sub>1c</sub> test. We ascertained provider specialty on the basis of the provider specialty code. Cholesterol, creatinine, and HbA<sub>1c</sub> tests obtained on the same day (with or without fasting plasma glucose or urine microalbumin) were categorized as a bundled test. Web appendix 1 presents the CPT codes used to identify these studies.

#### Statistical analysis

We calculated frequencies and means for baseline characteristics and diabetes management stratified by testing frequency or baseline HbA<sub>1c</sub>. Comparisons were tested by  $\chi^2$  test for categorical variables and *t* test for continuous variable. Time to repeat HbA<sub>1c</sub> testing was calculated, and the distribution was graphed, stratified by testing frequency.

We computed odds ratios and 95% confidence intervals by modeling logistic regression with the dependent variable as the odds of testing excessively and frequently (versus testing according to the guidelines). We also computed odds ratios and 95% confidence intervals for the odds of treatment intensification and deintensification (versus no change or drug class change only) of the two categories indicative of too many tests compared with guideline recommended frequency. Odds of treatment intensification were assessed among all patients in the cohort, while odds of treatment deintensification were assessed only among those patients receiving at least one diabetes drug at baseline. For all analyses, two sided P values less than 0.05 were considered significant. We used SAS software version 9.3 (SAS Institute) for all analyses.

## Results

### Study population

Table 1 describes the baseline characteristics of 31545 patients included in the study. The cohort had a mean age of 58 years (standard deviation 11), and a mean index HbA<sub>1c</sub> of 6.2% (0.4); 61.5% of patients had low disease burden as judged by the Charlson index; and 83.7% received care from both primary care providers and medical subspecialists. Distribution of HbA<sub>1c</sub> results at the time of index testing showed that 10.4% of patients had HbA<sub>1c</sub> levels of at least 5.6%; 57.1% had HbA<sub>1c</sub> between 5.7% and 6.4%; and 32.5% had HbA<sub>1c</sub> between 6.5% and 6.9%. Furthermore, at the time of the index HbA<sub>1c</sub> test, 32.9% of patients did not receive any glucose lowering drugs, 37.7% were treated with one drug, 21.3% were treated with two drugs, and 8.2% were treated with three or more drugs.

### Testing frequency

Most patients received frequent (54.5%) or excessive (5.8%) HbA<sub>1c</sub> testing (table 1). The figure shows the median time to retesting following the index HbA<sub>1c</sub> test in each group. These times were four weeks, 12 weeks, and 27 weeks for patients receiving excessive, frequent, and guideline recommended testing, respectively.

**Table 1 | Baseline distribution of HbA<sub>1c</sub> testing frequencies in patients with stable and controlled type 2 diabetes. Data are no (%) of patients per testing frequency category**

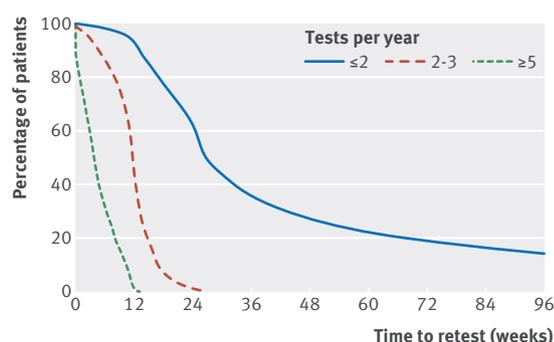
	HbA <sub>1c</sub> testing frequency			P
	Recommended (≤2 per year)	Frequent (3-4 per year)	Excessive (≥5 per year)	
Patients in each testing category (n=31 545; 100%)	12 535 (39.7)	17 182 (54.5)	1828 (5.8)	—
Patient age (years)				
18-44 (n=3561; 11.3%)	1711(48.1)	1684 (47.3)	166 (4.7)	<0.001
45-54 (n=8130; 25.8%)	3404 (41.9)	4314 (53.1)	412 (5.1)	
55-64 (n=11 781; 37.4%)	4502 (38.2)	6586 (55.9)	693 (5.9)	
65-74 (n=4643; 14.7%)	1660 (35.8)	2666 (57.4)	317 (6.8)	
≥75 (n=3430; 10.9%)	1258 (36.7)	1932 (56.3)	240 (7.0)	
Sex				
Male (n=16 060; 50.9%)	6448 (40.2)	8664 (53.9)	948 (5.9)	0.16
Female (n=15 485; 49.1%)	6087 (39.3)	8518 (55.0)	880 (5.7)	
Race or ethnic origin				
White (n=18 190; 57.7%)	7242 (39.8)	9919 (54.5)	1029 (5.7)	<0.001
Black (n=4757; 15.1%)	2042 (42.9)	2481 (52.2)	234 (4.9)	
Hispanic (n=3482; 11.0%)	1442 (41.4)	1852 (53.2)	188 (5.4)	
Asian (n=2243; 7.1%)	834 (37.2)	1280 (57.1)	129 (5.8)	
Unknown (n=2873; 9.1%)	975 (33.9)	1650 (57.4)	248 (8.6)	
US census region				
Midwest (n=3675; 11.7%)	1545 (42.0)	1985 (54.0)	145 (4.0)	<0.001
Northeast (n=7954; 25.2%)	2782 (35.0)	4467 (56.2)	705 (8.9)	
South (n=17 481; 55.4%)	7113 (40.7)	9512 (54.4)	856 (4.9)	
West (n=2433; 7.7%)	1095 (45.0)	1217 (50.0)	121 (5.0)	
Unknown (n=2; 0.0%)	0	1 (50.0)	1 (50.0)	
Comorbidities				
Myocardial infarction (n=383; 1.2%)	125 (32.6)	227 (59.3)	31 (8.1)	0.01
Heart failure (n=720; 2.3%)	251 (34.9)	403 (56.0)	66 (9.2)	<0.001
Kidney disease (n=655; 2.1%)	211 (32.2)	372 (56.8)	72 (11.0)	<0.001
Cancer (n=2073; 6.6%)	728 (35.1)	1176 (56.7)	169 (8.2)	<0.001
Charlson comorbidity index				
0-1 (n=19 411; 61.5%)	8316 (42.8)	10225 (52.7)	870 (4.5)	<0.001
2 (n=4814; 15.3%)	1836 (38.1)	2646 (55.0)	332 (6.9)	
3 (n=4316; 13.7%)	1468 (34.0)	2515 (58.3)	333 (7.7)	
≥4 (n=3004; 9.5%)	915 (30.5)	1796 (59.8)	293 (9.8)	
Index HbA <sub>1c</sub>				
≤5.6% (n=3283; 10.4%)	1599 (48.7)	1498 (45.6)	186 (5.7)	<0.001
5.7-6.4% (n=18 016; 57.1%)	7445 (41.3)	9601 (53.3)	970 (5.4)	
6.5-6.9% (n=10 246; 32.5%)	3491 (34.1)	6083 (59.4)	672 (6.6)	
Baseline treatment				
Lifestyle (n=10 370; 32.9%)	4798 (46.3)	5069 (48.9)	503 (4.9)	<0.001
1 drug (n=11 883; 37.7%)	4617 (38.9)	6572 (55.3)	694 (5.8)	
2 drugs (n=6711; 21.3%)	2383 (35.5)	3920 (58.4)	408 (6.1)	
≥3 drugs (n=2581; 8.2%)	737 (28.6)	1621 (62.8)	223 (8.6)	
Treatment change				
No change before or after; lifestyle (n=8976; 28.5%)	4245 (47.3)	4328 (48.2)	403 (4.5)	<0.001
No change before or after; treated with at least one drug (n=16 746; 53.1%)	6246 (37.3)	9546 (57.0)	954 (5.7)	
Drug class change only (n=247; 0.8%)	59 (23.9)	158 (64.0)	30 (12.2)	
Intensification (n=2644; 8.4%)	900 (34.0)	1515 (57.3)	229 (8.7)	
Deintensification (n=2932; 9.3%)	1085 (37.0)	1635 (55.8)	212 (7.2)	
Specialties seen*				
Primary care (n=30 331; 96.2%)	12 062 (39.8)	16 554 (54.6)	1715 (5.7)	<0.001
Endocrinology (n=4225; 13.4%)	1044 (24.7)	2626 (62.2)	555 (13.1)	<0.001
Cardiology (n=8237; 26.1%)	2828 (34.3)	4755 (57.7)	654 (7.9)	<0.001
Ophthalmology (n=5772; 18.3%)	1967 (34.1)	3396 (58.8)	409 (7.1)	<0.001
Gynecology (n=6601; 20.9%)	2462 (37.3)	3717 (56.3)	422 (6.4)	<0.001
Nephrology (n=1433; 4.5%)	419 (29.2)	838 (58.5)	176 (12.3)	<0.001
Laboratory studies obtained on the same day				
HbA <sub>1c</sub> with or without glucose (n=16 149; 51.2%)	5866 (36.3)	9115 (56.4)	1168 (7.2)	<0.001
Bundled tests (n=15 396; 48.8%)†	6669 (43.3)	8067 (52.4)	660 (4.3)	

(Continued)

**Table 1 | Baseline distribution of HbA<sub>1c</sub> testing frequencies in patients with stable and controlled type 2 diabetes. Data are no (%) of patients per testing frequency category**

	HbA <sub>1c</sub> testing frequency			P
	Recommended (≤2 per year)	Frequent (3-4 per year)	Excessive (≥5 per year)	
<b>Coordination of care</b>				
Primary care only (n=3927; 12.5%)	1906 (48.5)	1909 (48.6)	112 (2.9)	<0.001
Primary care and specialist care (n=26 404; 83.7%)	10 156 (38.5)	14 645 (55.5)	1603 (6.1)	
Specialist care only (n=1109; 3.5%)	436 (39.3)	576 (51.9)	97 (8.8)	
None (n=105; 0.3%)	37 (35.2)	52 (49.5)	16 (15.2)	
<b>Encounters per year</b>				
Median (interquartile range)	5.5 (3.5-9.0)	7.5 (5.0-11.5)	11.0 (7.5-16.0)	<0.001
Range	0.0-76.5	0.0-73.0	0.0-124.0	
<b>Year of index HbA<sub>1c</sub> test</b>				
2001-02 (n=776; 2.5%)	220 (28.4)	485 (62.5)	71 (9.5)	<0.001
2003-04 (n=1827; 5.8%)	750 (41.1)	978 (53.5)	99 (5.5)	
2005-06 (n=2922; 9.3%)	1258 (43.1)	1498 (51.3)	166 (5.7)	
2007-08 (n=9203; 29.2%)	3240 (35.2)	5345 (58.1)	618 (6.8)	
2009-10 (n=12 648; 40.1%)	5261 (41.6)	6697 (53.0)	690 (5.5)	
2011 (n=4169; 13.2%)	1806 (43.3)	2179 (52.3)	184 (4.4)	

\*Each patient could see different specialties of healthcare providers, and could be included in one or more categories; percentages therefore add up to more than 100%.  
†Bundled tests include lipid profile (n=10 668; 33.8%) and serum creatinine with or without urine microalbumin (n=4728; 15.0%).



**Median times to HbA<sub>1c</sub> retesting in study population following an index test that was at glycemic goal (that is, HbA<sub>1c</sub> < 7.0%)**

Patients receiving too many tests (for example, excessive and frequent testing frequencies) were older, had more comorbid conditions, were taking more diabetes drugs, and had higher index HbA<sub>1c</sub> (all  $P < 0.001$ ; table 1). There was a small amount of variability in testing frequency as a function of race, with a lower proportion of black (4.9%) and Hispanic (5.4%) patients undergoing excessive testing than white (5.7%) and Asian (5.8%) patients ( $P < 0.001$ ). There was significant geographical variability in excessive testing, with the highest prevalence in the northeast US census region (8.9%) and the lowest prevalence in the midwest region (4.0%).

In the multivariable analysis, the odds of frequent and excessive testing as compared with guideline recommended testing increased with patient complexity. This increase was reflected by the Charlson comorbidity index ( $\geq 4$ ), treatment ( $\geq$  three diabetes drugs), index HbA<sub>1c</sub> (6.5-6.9%), and involvement of an endocrinologist or nephrologist in the patient's care (table 2). There was also direct correlation between the number of discrete healthcare providers seen by the patient annually and the likelihood of excessive and frequent testing; each additional provider increased the odds of being

tested (odds ratio 1.14 (95% confidence interval 1.10 to 1.18) and 1.05 (1.04 to 1.07)) for receiving excessive and frequent testing compared with guidance recommended testing. Patients living in the northeast US census region had significantly higher odds of undergoing excessive testing than those living in the south region (1.60 (1.44 to 1.78)), while patients living in the midwest region were significantly less likely (0.67 (0.58 to 0.79)). Finally, use of bundled testing decreased the odds of excessive testing compared with use of glycemic tests alone (0.82 (0.77 to 0.88)).

#### Treatment changes in response to testing

Most patients (81.6%) in the study did not have their treatment altered after the index HbA<sub>1c</sub> test (table 1). However, despite meeting recommended targets for glycemic control as per study inclusion criteria, treatment was further intensified by addition of glucose lowering drugs or insulin in 13% (n=229), 9% (n=1515), and 7% (n=900) of patients tested excessively, frequently, and per the guidelines, respectively ( $P < 0.001$ ; table 1).

We specifically examined the rates of excessive testing among patients as a function of treatment change at the time of index HbA<sub>1c</sub> testing (table 1). Of the 31 545 patients included in the study, 8976 (28.5%) did not receive any glucose lowering drugs before or after the index HbA<sub>1c</sub> test. Yet of these patients, 403 (4.5%) were still tested excessively in the following two years. An additional 16 746 (53.1%) patients of the study population were treated with the same non-insulin drugs before and after testing; of these patients, 954 (5.7%) continued to be tested excessively. Of 2644 (8.4%) patients whose regimens intensified after the index test, 229 (8.7%) were tested excessively. Finally, of 2932 (9.3%) patients whose treatments deintensified, 212 (7.2%) were tested excessively.

Compared with testing rates among patients who remained on the same treatment regimen after the index HbA<sub>1c</sub> test, excessive testing was significantly less

Table 2 | Correlates of increased frequency of HbA<sub>1c</sub> testing

	Excessive HbA <sub>1c</sub> testing		Frequent HbA <sub>1c</sub> testing	
	Odds ratio (95% CI)	P	Odds ratio (95% CI)	P
Patient age (years)				
18-44	Ref	Ref	Ref	Ref
45-54	0.94 (0.85 to 1.05)	0.29	0.97 (0.93 to 1.02)	0.23
55-64	1.08 (0.98, 1.19)	0.10	1.07 (1.03 to 1.12)	<0.001
65-74	1.17 (1.03 to 1.32)	0.01	1.12 (1.06 to 1.19)	<0.001
≥75	1.10 (0.95 to 1.27)	0.21	1.07 (1.00 to 1.15)	0.05
Sex				
Male	Ref	Ref	Ref	Ref
Female	0.95 (0.89 to 1.02)	0.13	0.98 (0.96 to 1.01)	0.22
Race				
White	Ref	Ref	Ref	Ref
Non-white	0.99 (0.93 to 1.04)	0.64	0.99 (0.97 to 1.01)	0.40
US census region				
South	Ref	Ref	Ref	Ref
Midwest	0.67 (0.58 to 0.79)	<0.001	0.95 (0.90 to 1.01)	0.12
Northeast	1.60 (1.44 to 1.78)	<0.001	1.14 (1.08 to 1.19)	<0.001
West	1.01 (0.86 to 1.18)	0.93	0.90 (0.84 to 0.97)	0.004
Year of index HbA <sub>1c</sub> test				
2001-02	Ref	Ref	Ref	Ref
2003-04	0.95 (0.78 to 1.16)	0.61	0.93 (0.85 to 1.01)	0.09
2005-06	0.97 (0.83 to 1.14)	0.73	0.86 (0.80 to 0.92)	<0.001
2007-08	1.11 (0.99 to 1.24)	0.08	1.10 (1.05 to 1.16)	<0.001
2009-10	0.74 (0.67 to 0.83)	<0.001	0.85 (0.80 to 0.89)	<0.001
2011	0.54 (0.46 to 0.64)	<0.001	0.77 (0.72 to 0.83)	<0.001
Index HbA <sub>1c</sub>				
≤5.6%	Ref	Ref	Ref	Ref
5.7-6.4%	0.95 (0.88 to 1.03)	0.19	1.02 (0.99 to 1.06)	0.22
6.5-6.9%	1.29 (1.18 to 1.41)	<0.001	1.31 (1.26 to 1.37)	<0.001
Charlson comorbidity index				
0-1	Ref	Ref	Ref	Ref
2	0.97 (0.87 to 1.09)	0.65	0.98 (0.93 to 1.03)	0.43
3	0.99 (0.88 to 1.10)	0.82	1.03 (0.98 to 1.09)	0.23
≥4	1.44 (1.29 to 1.61)	<0.001	1.15 (1.08 to 1.22)	<0.001
Laboratory studies obtained on the same day				
HbA <sub>1c</sub> with or without glucose	Ref	Ref	Ref	Ref
Bundled tests	0.82 (0.77 to 0.88)	<0.001	0.93 (0.90 to 0.95)	<0.001
Baseline treatment				
Lifestyle	Ref	Ref	Ref	Ref
1 drug	0.95 (0.87 to 1.03)	0.21	0.95 (0.92 to 0.99)	0.02
2 drugs	1.05 (0.95 to 1.16)	0.38	1.08 (1.03 to 1.14)	<0.001
≥3 drugs	1.61 (1.41 to 1.85)	<0.001	1.39 (1.29 to 1.49)	<0.001
Treatment change				
No change	Ref	Ref	Ref	Ref
Deintensification	0.78 (0.65 to 0.93)	0.004	0.80 (0.73 to 0.88)	<0.001
Intensification	1.24 (1.03 to 1.49)	0.02	1.09 (0.98 to 1.20)	0.12
Drug class change only	1.53 (1.04 to 2.25)	0.03	1.32 (1.05 to 1.67)	0.02
No of healthcare providers per year	1.14 (1.10 to 1.18)	<0.001	1.05 (1.04 to 1.07)	<0.001
Coordination of care				
Primary care only	Ref	Ref	Ref	Ref
Primary care and specialist care	0.73 (0.60 to 0.87)	<0.001	1.02 (0.91 to 1.15)	0.72
Specialist care only	0.70 (0.55 to 0.90)	0.006	0.77 (0.67 to 0.90)	<0.001
None	3.24 (2.01 to 5.24)	<0.001	1.31 (0.94 to 1.81)	0.11
Specialties seen				
Endocrinology	1.87 (1.75 to 2.00)	<0.001	1.34 (1.29 to 1.40)	<0.001
Cardiology	1.04 (0.98 to 1.11)	0.19	1.03 (1.00 to 1.06)	0.06
Ophthalmology	1.06 (0.99 to 1.14)	0.09	1.07 (1.03 to 1.10)	<0.001
Gynecology	1.03 (0.95 to 1.12)	0.41	1.05 (1.02 to 1.09)	0.006
Nephrology	1.36 (1.23 to 1.52)	<0.001	1.09 (1.02 to 1.16)	0.008

Data are odds ratios and 95% confidence intervals (CI) of excessive and frequent testing, versus guideline recommended testing. Ref=reference group.

likely among patients whose treatments deintensified (odds ratio 0.78 (95% confidence interval 0.65 to 0.93)). On the other hand, excessive testing was significantly more likely among patients who switched drug classes (1.53 (1.04 to 2.25)) or whose treatments intensified (1.24 (1.03 to 1.49); table 2).

Table 3 presents the correlates of treatment intensification and deintensification. Patients who were tested excessively were significantly more likely to have treatment intensified after the index HbA<sub>1c</sub> test (odds ratio 1.35 (95% confidence interval 1.22 to 1.50)) but not deintensified (1.08 (0.97 to 1.20)). Older age was associated with decreased odds of both treatment intensification and deintensification, while comorbidity burden was not associated with either. Additional predictors of treatment intensification included care by an endocrinologist (1.27 (1.20 to 1.34)), and HbA<sub>1c</sub> levels of 6.5-6.9% versus 5.6% or under (1.72 (1.61 to 1.85)).

### Temporal trends

Testing frequency varied over the course of the study, and the prevalence of both excessive and frequent testing decreased significantly after 2009 (tables 1 and 2). Excessive testing rates were unchanged in 2003-08 compared with 2001-02 (all  $P > 0.05$ ), but excessive testing was less likely in 2009-10 (odds ratio 0.74 (95% confidence interval 0.67 to 0.83)) and 2011 (0.54 (0.46 to 0.63); table 2). Trends for treatment intensification were similar, with no significant change in 2003-08 compared with 2001-02, but showed a reduction after 2009. Compared with 2001-02, the odds of treatment intensification were 0.80 (95% confidence interval 0.74 to 0.87) in 2009-10 and 0.79 (0.70 to 0.89) in 2011 (table 3). We saw no significant change over time in the likelihood of treatment deintensification.

## Discussion

### Principal findings

In this study, we looked at a national cohort of 31545 adults with type 2 diabetes in the USA who had achieved and maintained stable glycemic control with HbA<sub>1c</sub> less than 7.0%, had no use of insulin, and had no apparent indications for intensive monitoring or treatment. In this cohort, more than 60% of patients received too many HbA<sub>1c</sub> tests despite current guidance recommendations of one or two tests per year.<sup>4-10</sup> In total, we found that 5.8% of patients had five or more tests over one year, and 54.5% had three or four tests over one year. We also identified a direct association between excessive testing and likelihood of treatment intensification that, in the context of HbA<sub>1c</sub> being already less than 7%, is concerning for overtreatment. In 2008, the US National Quality Forum designated unnecessary laboratory tests to be one of nine areas of wasteful or inappropriate care,<sup>22</sup> potentially explaining the recent improvements in excessive testing rates in our patient population seen after 2009.

### Strengths and limitations of the study

To our knowledge, this is the largest national study of glycemic overtesting among clinically stable and con-

trolled people with diabetes, and includes commercially insured adults of all ages from across the USA. While the study population is not representative of all patients with diabetes, it was specifically chosen to reflect clinical situations where the frequency of guideline recommended HbA<sub>1c</sub> testing should suffice. It is likely that the prevalence of overtesting would have been even greater had all patients with diabetes been included, as in previous studies. Finally, the study population is representative of commercially insured adults in the USA, but not of the entire US population, because it does not include those insured by government payers.

This study focused on patients who had at least one HbA<sub>1c</sub> test performed during the study period. Although we could assess clinical overuse as a result, we could not capture the prevalence of underuse. Study design was also based on the assumption that frequent monitoring was not needed for patients with non-insulin treated type 2 diabetes who have stable HbA<sub>1c</sub> within the target range, are not pregnant, and have no documented hypoglycemia or hyperglycemia. It is possible that such patients experienced deterioration of glycemic control during the study, warranting an increase in testing frequency. However, testing frequency in routine clinical practice is determined prospectively, using population level data to infer the likelihood of glycemic deterioration or new instances of hypoglycemic and hyperglycemic acute diabetes complications. Our study was restricted to patients whose histories did not warrant frequent testing, so that their repeat HbA<sub>1c</sub> test should have been scheduled six to 12 months after the index test, rather than one or three months after—as we observed for patients in the excessive and frequent testing groups, respectively. Finally, self-reported hypoglycemia—which is known to impair quality of life<sup>23</sup> and increase risk of mortality,<sup>24</sup> or glycemic variability on glucose self-monitoring—could have prompted glycemic testing but remain unseen in our data sources. However, because self-reporting of hypoglycemia<sup>24</sup> and glycemic variability do not always correlate with HbA<sub>1c</sub>, additional testing in these situations might not be helpful.

In view of these limitations, this study is the largest and (by virtue of strict inclusion and exclusion criteria to only include individuals at the lowest risk) most rigorous of glycemic overtesting among US patients so far. This was made possible by the large number of patients and clinical data available in the OLDW dataset, and is therefore generalizable to other commercially insured adults in the USA.

### Comparison with other studies

Our findings confirm observations from previous studies that detected redundant HbA<sub>1c</sub> testing; however, none of these studies explicitly differentiated between patients who needed close monitoring and those who did not.<sup>5,11,25-27</sup> The geographical variability of excessive HbA<sub>1c</sub> testing also parallels other areas of healthcare overuse,<sup>28</sup> suggesting non-clinical and patient unrelated factors driving such laboratory overuse. This observation warrants closer examination of institutional and individual clinical practices that might

**Table 3 | Correlates of treatment regimen change after index HbA<sub>1c</sub> testing**

	Treatment intensification		Treatment deintensification	
	Odds ratio (95% CI)	P	Odds ratio (95% CI)	P
<b>Patient age (years)</b>				
18-44	Ref	Ref	Ref	Ref
45-54	1.13 (1.04 to 1.23)	0.003	1.08 (1.00 to 1.17)	0.04
55-64	1.06 (0.99 to 1.14)	0.10	0.93 (0.87 to 1.00)	0.04
65-74	0.92 (0.83 to 1.02)	0.10	0.92 (0.84 to 1.02)	0.11
≥75	0.70 (0.62 to 0.80)	<0.001	0.84 (0.74 to 0.95)	0.005
<b>Sex</b>				
Male	Ref	Ref	Ref	Ref
Female	1.06 (1.01 to 1.11)	0.03	1.06 (1.01 to 1.11)	0.02
<b>Race</b>				
White	Ref	Ref	Ref	Ref
Non-white	1.00 (0.95 to 1.04)	0.82	1.07 (1.03 to 1.11)	0.002
<b>US census region</b>				
South	Ref	Ref	Ref	Ref
Midwest	0.79 (0.70 to 0.88)	<0.001	0.93 (0.83 to 1.04)	0.18
Northeast	0.90 (0.83 to 0.98)	0.01	0.96 (0.88 to 1.04)	0.34
West	1.28 (1.14 to 1.44)	<0.001	1.09 (0.97 to 1.21)	0.18
<b>Year of index HbA<sub>1c</sub> test</b>				
2001-02	Ref	Ref	Ref	Ref
2003-04	0.90 (0.77 to 1.05)	0.18	0.89 (0.75 to 1.05)	0.15
2005-06	1.07 (0.95 to 1.20)	0.28	1.02 (0.89 to 1.17)	0.75
2007-08	0.97 (0.89 to 1.05)	0.40	1.04 (0.94 to 1.15)	0.45
2009-10	0.80 (0.74 to 0.87)	<0.001	1.15 (1.04 to 1.27)	0.007
2011	0.79 (0.70 to 0.89)	<0.001	1.26 (1.11 to 1.42)	<0.001
<b>Index HbA<sub>1c</sub></b>				
≤5.6%	Ref	Ref	Ref	Ref
5.7-6.4%	0.88 (0.82 to 0.93)	<0.001	0.96 (0.91 to 1.02)	0.21
6.5-6.9%	1.72 (1.61 to 1.85)	<0.001	0.79 (0.74 to 0.84)	<0.001
<b>Charlson comorbidity index</b>				
0-1	Ref	Ref	Ref	Ref
2	1.02 (0.94 to 1.12)	0.59	0.97 (0.89 to 1.07)	0.56
3	1.01 (0.92 to 1.11)	0.85	1.00 (0.91 to 1.09)	0.92
≥4	1.04 (0.94 to 1.15)	0.42	1.07 (0.97 to 1.18)	0.15
<b>Frequency of HbA<sub>1c</sub> testing</b>				
Recommended (≤2 tests/year)	Ref	Ref	Ref	Ref
Frequent (3-4 tests/year)	0.96 (0.90 to 1.03)	0.23	0.92 (0.86 to 0.98)	0.009
Excessive (≥5 tests/year)	1.35 (1.22 to 1.50)	<0.001	1.08 (0.97 to 1.20)	0.18
No of healthcare providers per year	1.01 (0.98 to 1.04)	0.51	1.05 (1.02 to 1.09)	<0.001
<b>Baseline treatment</b>				
Lifestyle	Ref	Ref	—	—
1 drug	0.80 (0.74 to 0.86)	<0.001	Ref	Ref
2 drugs	0.79 (0.72 to 0.87)	<0.001	0.84 (0.79 to 0.89)	<0.001
≥3 drugs	0.80 (0.70 to 0.92)	0.001	2.30 (2.15 to 2.45)	<0.001
<b>Specialties involved</b>				
Endocrinology	1.27 (1.20 to 1.34)	<0.001	1.05 (0.99 to 1.11)	0.09
Cardiology	1.01 (0.96 to 1.06)	0.68	0.96 (0.91 to 1.01)	0.11
Ophthalmology	1.01 (0.95 to 1.06)	0.80	0.95 (0.90 to 1.00)	0.07
Gynecology	0.94 (0.89 to 1.00)	0.06	1.01 (0.95 to 1.08)	0.68
Nephrology	1.09 (0.99 to 1.20)	0.09	1.10 (1.01 to 1.20)	0.04

Odds ratio compares the odds of treatment intensification or deintensification after index HbA<sub>1c</sub> test with either no treatment change or drug class change only. The intensification group includes all patients, while the deintensification group includes only those patients receiving at least one glucose lowering drug at baseline.

CI=confidence interval; Ref=reference group.

promote frequent testing.<sup>29</sup> Further investigation should also look at any similar overtesting trends in other disciplines and clinical circumstances, reinforcing the culture of test reliance and high healthcare use.

### Conclusions and policy implications

Excessive HbA<sub>1c</sub> testing is ineffective and inefficient, and could contribute to the growing problem of waste

in healthcare and increasing patient burden in the management of type 2 diabetes.<sup>25-30</sup> Our study did not directly quantify the excess costs incurred by overtesting, which would include the direct cost of HbA<sub>1c</sub> tests as well as the indirect costs of phlebotomy and laboratory services, patient time, and burden of completing testing (especially when bundled with a fasting lipid panel). Because HbA<sub>1c</sub> is a measure of average glycemia

over three months, more frequent monitoring is also not representative of steady state glycemic control and is generally not clinically informative.

There are several potential reasons for frequent testing. These include clinical uncertainty; misunderstanding of the nature of the test (for example, the fact that HbA<sub>1c</sub> represents three months of glycemic control, on average); desire for diagnostic and management thoroughness; fragmentation of care; and the need to fulfill patient, institution, and regulatory demands.<sup>31,32</sup> Inefficiency can result from inadequate care coordination between different healthcare providers involved in a patient's care.<sup>17</sup> This inefficiency was evident in our study, because the odds of redundant testing increased with the number of doctors seen per year. Some specialists, particularly endocrinologists, could be accustomed to seeing high risk patients who need frequent monitoring, and extend those practices to patients who might be at lower risk. Public reporting of diabetes performance measures and performance based reimbursement could also drive repeat testing, although this was less likely to influence testing frequency in our study where all patients had already satisfied the reporting criterion of HbA<sub>1c</sub> levels being less than 7.0%.

Clinically unnecessary testing can have detrimental effects for both the patient and the healthcare system. Excessive tests can cause unnecessary patient discomfort and anxiety, and because of the potential for false positive results caused by expected short term biological and analytical variability of the HbA<sub>1c</sub> test,<sup>33</sup> they can increase the risk of further needless testing, specialist referral, and treatment change.<sup>34</sup> Availability of a laboratory result could compel a doctor and patient to act, even if not clinically indicated or beneficial. We saw this in our study population, in which excessive testing was associated with an increased likelihood of treatment intensification despite normal levels of HbA<sub>1c</sub>.

We found that patients over age 65 years and those with high underlying disease burden were more likely to have excessive HbA<sub>1c</sub> testing. Healthcare providers could have decided that such patients needed to be monitored more closely, yet all these patients had stable HbA<sub>1c</sub> levels of less than 7.0%, with no insulin use or documented hypoglycemia or hyperglycemia. Moreover, current guidelines recommend that patients with significant comorbidities should in fact be treated less intensely and have relaxed HbA<sub>1c</sub> targets above 7.0%,<sup>4-10</sup> making frequent testing in this population even less useful. We were reassured to find that patients aged 75 years and older were less likely to have intensified treatment after the index HbA<sub>1c</sub> test than those younger than 45 years. But these older patients were also less likely to have deintensified treatment after the index HbA<sub>1c</sub> test, suggesting a propensity to maintain the status quo (for example, clinical inertia) in this tightly controlled population.

The association between overtesting and potential overtreatment is concerning, particularly considering clinical trial data linking intensive glucose lowering treatment to adverse health outcomes, including hypoglycemia, cardiovascular events, and mortality.<sup>35-39</sup> Because all study patients had index HbA<sub>1c</sub> levels lower than

7.0% at study entry, none was eligible for treatment intensification, and some were eligible for treatment deintensification (particularly if they are overwhelmed by treatment burden or hypoglycemia). Thus, all treatment intensification observed during our study was not warranted and is, in essence, overtreatment. The implications of such overtreatment needs further work to identify whether it results in direct patient harm, specifically hypoglycemia and other adverse drug reactions, in addition to burden of polypharmacy and increased healthcare use. The reasons for overtreatment, particularly treatment intensification, should be further investigated through qualitative analysis of patient, provider, and system factors leading to overtesting, overtreatment, and increased healthcare use.

In 2012, the American Board of Internal Medicine Foundation launched the Choosing Wisely campaign, aimed at reducing healthcare waste from low value, unnecessary, or redundant tests and procedures.<sup>40</sup> Although HbA<sub>1c</sub> testing was not included among the "five things physicians and patients should question," doctors were cautioned against excessive frequency of self-glucose monitoring in adults with stable type 2 diabetes.<sup>40</sup> We argue that the same caution should be applied to HbA<sub>1c</sub> testing and other routine chronic disease management tests. Ultimately, patients and doctors should question the value of routine tests and test bundles, increasingly built as defaults within protocols and algorithms to improve compliance with quality metrics and performance in those metrics. Doing so could reduce the waste associated with marginally informative and otherwise excessive testing, and might also mitigate the practice of responding to small variations in test results with equally unwarranted and excessive treatment changes. Unnecessary testing is not only wasteful, but also potentially harmful to patients.

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**Data sharing statement:** Technical appendix, statistical code, and dataset are available from the corresponding author at [mccoey.rozalina@mayo.edu](mailto:mccoey.rozalina@mayo.edu).

The lead author and the manuscript's guarantor (RGM) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned have been explained.

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**Web appendix: Supplemental materials**