Glycemic Control From 1988 to 2000 Among U.S. Adults Diagnosed With Type 2 Diabetes

A preliminary report

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OBJECTIVE — To describe the changes in demographics, antidiabetic treatment, and glycemic control among the prevalent U.S. adult diagnosed type 2 diabetes population between the National Health and Nutrition Examination Survey (NHANES) III (1988–1994) and the initial release of NHANES 1999–2000.

RESEARCH DESIGN AND METHODS — The study population was derived from NHANES III ($n = 1,215$) and NHANES 1999–2000 ($n = 372$) subjects who reported a diagnosis of type 2 diabetes with available data on diabetes medication and HbA_{1c}. Four therapeutic regimens were defined: diet only, insulin only, oral antidiabetic drugs (OADs) only, or OADs plus insulin. Multiple logistic regression was used to examine changes in antidiabetic regimens and glycemic control rates over time, adjusted for demographic and clinical risk factors. The outcome measure for glycemic control was HbA_{1c}. Glycemic control rates were defined as the proportion of type 2 diabetic patients with HbA_{1c} level <7%.

RESULTS — Dietary treatment in individuals with diabetes decreased as the sole therapy from 27.4 to 20.2% between the surveys. Insulin use also decreased from 24.2 to 16.4%, while those on OADs only increased from 45.4 to 52.5%. Combination of OADs and insulin increased from 3.1 to 11.0%. Glycemic control rates declined from 44.5% in NHANES III (1988–1994) to 35.8% in NHANES 1999–2000.

CONCLUSIONS — Treatment regimens among U.S. adults diagnosed with type 2 diabetes have changed substantially over the past 10 years. However, a decrease in glycemic control rates was also observed during this time period. This trend may contribute to increased rates of macrovascular and microvascular diabetic complications, which may impact health care costs. Our data support the public health message of implementation of early, aggressive management of diabetes.

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Inadequate glycemic control among individuals with diabetes constitutes a major public health problem in the U.S. Uncontrolled diabetes is associated with premature death and disability as well as decreased quality of life and significantly adds to national medical health care expenditures (1). Recent estimates show that the minimum direct and indirect expenditures attributable to diagnosed diabetes in 2002 were $132 billion (2). Glycemic control remains the major therapeutic objective for prevention of target organ damage and other complications arising from diabetes. Studies have shown that a comprehensive and aggressive management approach is effective in decreasing the rate of progression of microvascular complications (3). Treatment regimens of diet and exercise, insulin, and oral hypoglycemic agents are known to improve glycemia (4,5), and current approaches to disease management that include greater patient self-participation are recommended (6,7).

However, the adequacy of adherence to American Diabetes Association guidelines, as reflected in estimates of glycemic control (8), have not been published recently for the U.S. population. A study of U.S. adults sampled from 1988 to 1994 reported that the glycemic control rate was only 44.6% among patients with diagnosed type 2 diabetes (9). Recently, the initial 1999–2000 National Health and Nutrition Examination Survey (NHANES) data have been released, providing an opportunity for further analysis. This report describes the changes in demographics, general drug treatment, and glycemic control among the prevalent U.S. adult diagnosed type 2 diabetes population between NHANES III (1988–1994) and NHANES 1999–2000.

RESEARCH DESIGN AND METHODS

— The study population was derived from both the NHANES III (1988–1994) and the initial release of NHANES 1999–2000 (10). These surveys used a multistage cluster sample design to gather data about the health and nutritional status of the civilian noninstitutionalized population of the U.S. and have been described in detail elsewhere (11). For our analysis, we defined the study sample as the 1,686 subjects in NHANES III (1988–1994) and the 533 subjects in NHANES 1999–2000 aged ≥20 years who responded "yes" to the question "Other than during pregnancy, has a doctor ever told you that you had diabetes or sugar diabetes?" and in whom

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Abbreviations: OAD, oral antidiabetic drug; NHANES, National Health and Nutrition Examination Survey.

A table elsewhere in this issue shows conventional and Système International (SI) units and conversion factors for many substances.

HbA_{1c} had been measured. To limit the analysis to adults with diagnosed type 2 diabetes, we excluded subjects whose age at diagnosis was <30 years and who started insulin therapy within 1 year of diagnosis. We also excluded subjects for whom information on type of diabetes medication, BMI, or duration of diabetes was missing. After applying the exclusions, 1,215 subjects in NHANES III (1988–1994) and 372 subjects in NHANES 1999–2000 remained for analysis. We used the NHANES sampling weights and primary sampling units to estimate the number of individuals with diagnosed diabetes, by various demographic, treatment, and glycemic control groups, in the overall U.S. population.

Four antidiabetic therapeutic regimens were defined for this study: diet, insulin, oral antidiabetic drugs (OADs; monotherapy or in combination), and OADs plus insulin. These were defined according to a "yes" or "no" response to the following questions: "Are you now taking insulin?" and "Are you now taking diabetes pills?" We classified individuals who answered "no" to both of these questions as using diet-only therapy. The number and percent of adults diagnosed with type 2 diabetes on each therapeutic regimen was calculated, as was the estimate of those who achieved glycemic control using a cutpoint HbA_{1c} level <7% (8). Glycemic control rates were calculated as the proportion of type 2 diabetic patients with an HbA_{1c} level <7%. In NHANES III (1988–1994), HbA_{1c} was measured by high-performance liquid chromatography assay, as in the Diabetes Control and Complications Trial (12). The upper limit of normal for HbA_{1c} in the assay system is 6.1%, which is identical to the upper limit of normal recommended by the American Diabetes Association using the same assay system. Glycohemoglobin for NHANES 1999–2000 was measured using a Boronate Affinity High Performance Liquid Chromatography system (Primus, Kansas City, MO) (13), which has been standardized to the reference method used for the Diabetes Control and Complications Trial. Because the HbA_{1c} measurements were standardized to the same reference method, there were no differences in normal range or upper limit for HbA_{1c} in NHANES III (1988–1994) and NHANES 1999–2000.

In addition to univariate analysis, we used multiple logistic regression to examine whether demographics, treatment regimen, and other differences between the survey participants might explain any observed changes in national glycemic control rates between 1988 and 2000. In this logistic model, glycemic control was the dependent variable, the particular NHANES survey was the independent variable, and treatment regimen, age, sex, ethnicity, BMI, and duration of diabetes were potential confounding factors. In similar fashion, logistic models were used to determine whether changes in treatment regimens between the two surveys might be due to demographic and other differences between the surveys' participants rather than real temporal changes.

SUDAAN software (Research Triangle Institute, Research Triangle Park, NC) was used to account for the nonrandom cluster sample design in calculating variance estimates (14). Standard errors were computed for all prevalence rates via Taylor approximations. Using SAS statistical software (SAS Institute, Cary, NC), logistic regression models were run with sampling weights provided by the NHANES surveys, allowing population-based effect estimates. In the logistic models that included both surveys, it was not possible to calculate CIs for the effect estimates (odds ratios [ORs]), because the sampling methods of the two surveys differ.

Table 1—*Characteristics of the NHANES III (1988–1994) and NHANES 1999–2000 adult individuals with diagnosed type 2 diabetes*

	NHANES III (1988–1994)		NHANES 1999–2000	
	n	Percent (SE)	*n*	Percent (SE)
Sex				
Men	3,583,401	44.5 (2.28)	5,239,633	51.0 (3.81)
Women	4,475,506	55.5 (2.28)	5,024,989	49.0 (3.81)
Age				
20–44 years	1,132,544	14.1 (1.80)	1,678,957	16.4 (2.71)
45–64 years	3,445,461	42.8 (2.06)	4,625,426	45.1 (3.44)
≥65 years	3,480,903	43.2 (2.08)	3,960,240	38.6 (3.01)
Ethnicity				
Non-Hispanic whites	5,998,374	74.4 (1.92)	6,238,221	60.8 (5.07)
Non-Hispanic blacks	1,150,674	14.3 (1.33)	1,577,667	15.4 (2.55)
Mexican Americans	468,373	5.8 (0.44)	660,083	6.4 (1.12)
Other	441,486	5.5 (1.24)	1,788,651	17.4 (5.30)
Mean age (years)	61.3	(0.63)	59.0	(0.98)
Mean BMI (kg/m^2)	30.4	(0.24)	32.3	(0.82)
Mean duration since diagnosis of diabetes (years)	9.3	(0.43)	11.9	(1.02)
Mean HbA_{1c} (%)	7.7	(0.11)	7.9	(0.17)
Total	8,058,907	100.0	10,264,622	100.0

RESULTS — Changes in demographic and risk factor information between NHANES III (1988–1994) and NHANES 1999–2000 are described in Table 1. The number of prevalent cases of adults with diagnosed type 2 diabetes increased from 8.1 million in 1988–1994 to 10.3 million in 1999–2000. The proportion of men increased from 45% in NHANES III (1988–1994) to 51% in NHANES 1999–2000; individuals with diabetes in 1999–2000 were slightly younger than those in the earlier survey. The percentage of non-Hispanic whites among patients with diagnosed type 2 diabetes decreased from 74% in NHANES III (1988–1994) to 61% in NHANES 1999–2000. On the other hand, there was a slight increase in the percentage of non-Hispanic blacks and Mexican Americans, and the proportion of ethnic groups other than non-Hispanic whites, non-Hispanic blacks, and Mexican Americans increased from 6 to 17%. Mean BMI increased by 6% from 30.4 to 32.3 kg/m^2, the mean duration of diabetes increased by 28% from 9.3 to 11.9 years, and the mean HbA_{1c} increased by 3% from 7.7 to 7.9%.

Changes in therapeutic regimens between NHANES III (1988–1994) and NHANES 1999–2000 are shown in Table 2. The proportion of adults diagnosed with type 2 diabetes treated with insulin

Table 2—*Treatment of diagnosed adult type 2 diabetes in NHANES III (1988–1994) and NHANES 1999–2000*

	NHANES III (1988–1994)		NHANES 1999–2000		Adjusted* OR for medication use in NHANES 1999–2000 compared with NHANES III (1988–1994)
Medication type	*n*	Percent (SE)	*n*	Percent (SE)	
Insulin only	1,947,176	24.2 (1.49)	1,679,985	16.4 (3.11)	0.61
OADs only	3,655,259	45.4 (2.46)	5,384,943	52.5 (3.64)	1.50
Insulin and OADs	248,616	3.1 (0.51)	1,128,922	11.0 (2.90)	3.50
Diet alone	2,207,855	27.4 (2.00)	2,070,771	20.2 (3.18)	0.58
Total on all regimens	8,058,907	100	10,264,622	100.0	

*Adjusted for age, sex, ethnicity, BMI, and duration of diabetes.

only decreased from 24.2% (n = 1,947,176) in NHANES III (1988–1994) to 16.4% (n = 1,679,985) in NHANES 1999–2000. The likelihood of medication use in NHANES 1999–2000 relative to NHANES III, adjusted for potential confounders, is represented by the adjusted ORs in Table 2. The adjusting factors were age, sex, ethnicity, BMI, and duration of diabetes. An adjusted OR of 0.61 for insulin was found, indicating that the odds of being treated with insulin only decreased by 39% among the NHANES 1999–2000 survey participants compared with the NHANES III (1988–1994) participants. The proportion of subjects using only OADs increased over time (from 45.4% [n = 3,655,259] to 52.5% [n = 5,384,943]; OR 1.50). The use of insulin and OADs in combination increased from 3.1% (n = 248,616) to 11.0% (n = 1,128,922) (OR 3.50). Use of diet only decreased from 27.4% (n = 2,207,855) to 20.2% (n = 2,070,771) (OR 0.58).

The rate of glycemic control as defined by HbA_{1c} levels <7% was 44.5% for NHANES III (1988–1994) and 35.8% for NHANES 1999–2000. After adjustment for age, ethnicity, sex, BMI, medication use, and duration of diabetes, the odds of glycemic control was 21% lower in NHANES 1999–2000 compared with NHANES III (1988–1994) (OR 0.79; Table 3).

CONCLUSIONS — Our findings show that the proportion of adults in the U.S. with adequately controlled, diagnosed type 2 diabetes decreased between 1988 and 2000. Diabetes is controlled in only 36% of the more recent survey participants, despite recommendations for early diagnosis and aggressive treatment in recent years. We also observed changes in the demographic distribution of the adults with diagnosed type 2 diabetes from NHANES III (1988–1994) to NHANES 1999–2000, such as an increased proportion of men and minority groups other than non-Hispanic blacks and Mexican Americans. In recent years, individuals with diagnosed diabetes tended to be younger, to weigh more, and to have a longer duration of diabetes. However, we found that these demographic differences did not fully explain the lower glycemic control rates seen in recent years. Other reasons might account for the observed declining rates over time, such as changes in patient compliance with treatment programs despite more aggressive management. Another possible explanation for this observation may be surveillance bias due to a preferential increased screening for diabetes in high-risk individuals in the late 1990s compared with the previous decade.

Table 3—*Multiple logistic regression model of glycemic control between adults diagnosed with type 2 diabetes in NHANES 1999–2000 and NHANES III (1988–1994)*

Variable	OR for glycemic control*
Survey	
NHANES III	1.00
NHANES 1999–2000	0.79
Age	
20–44 years	1.00
45–64 years	1.34
≥65 years	1.58
Ethnicity	
Non-Hispanic whites	1.00
Non-Hispanic blacks	0.76
Mexican Americans	0.62
Other	0.72
Sex	
Men	1.00
Women	0.91
BMI (kg/m^2)	
<25	1.00
25 to <30	1.39
≥30	1.57
Medication use	
Diet	1.00
Insulin	0.14
OADs	0.25
Both insulin and OADs	0.08
Duration of diabetes (years)	1.01†

*Glycemic control defined as an HbA_{1c} level <7.0%; †for 1 additional year of diabetes duration.

In addition to changes in demographic features among patients over time, we also observed changes in the therapeutic regimen. The proportion of current individuals with diagnosed diabetes following diet-only or insulin-only treatment regimens has decreased since 1988–1994, but the proportion receiving OADs only or OADs in combination with insulin has increased. This change may be due to a larger selection of marketed oral agents. The increase in use of OADs from 1994 to 2000 is likely because only sulfonylureas were available in the earlier time period. By 2000, at least six new products in four new classes of OADs had become available. Another reason for the observed change may be a trend toward more aggressive and earlier treatment with OADs and OAD/insulin combinations.

We have also demonstrated that glycemic control was better in older individuals with diagnosed diabetes, those with higher BMI, and those with a longer duration of diagnosed diabetes (Table 3). Diabetic control was worse in minority ethnic groups and those taking medications (as compared with those on diet only). It is not clear why glycemic control might be better in older individuals, but

some studies have suggested that older patients may have better access to medical care, are more motivated to receive care, and are more compliant with medication use (15). This finding is somewhat in contrast to that of the U.K. Prospective Diabetes Study (UKPDS), which suggested that glycemic control rates among individuals with diabetes decrease with disease duration and, thus, with age (16). Also in contrast to the current study, Harris et al. (9) found that obesity was not related to glycemic control. They attributed their results to the cross-sectional design of the survey.

There are several limitations to the current analysis. The sample size from the NHANES 1999–2000 survey is small relative to NHANES III (1988–1994). As the survey continues over the next few years, more subjects will accrue, and the analysis can be repeated. Another limitation is that medication use is self-reported, and this may cause some misclassification in measured treatment regimens. Additionally, because NHANES surveys are cross-sectional in design, some of our findings may be related to survival bias in that individuals with diabetes having the poorest control may have died over time and could not participate in surveys. Also, in 1997, the American Diabetes Association changed the diagnostic criteria for diabetes, which may have influenced prevalence estimates of diagnosed diabetes between the two NHANES surveys (8).

We conclude that the proportion of adults in the U.S. with diagnosed type 2 diabetes that is controlled is inadequate and less favorable than in previous years. The cardiovascular and other consequences of inadequate glycemic control warrant serious consideration by treating physicians and others who care for individuals with diabetes. These data lend support to public health initiatives advocating early and aggressive management of diabetes.

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