

# Attainment of Goals from National Guidelines among Persons with Type 2 Diabetes: A Cohort Study in an Academic Family Medicine Setting

Julienne K. Kirk, PharmD, Kenneth R. Huber, MS, and C. Randall Clinch, DO, MS

## Abstract

**Background:** Cardiovascular disease is the leading cause of mortality in patients with diabetes, but goals for reduction of modifiable cardiovascular risk factors are difficult to achieve in primary care. We evaluated the change in risk factor control for a cohort of patients with diabetes and hyperlipidemia over a four-year period, as well as the change in proportion of patients meeting clinical practice guideline goals.

**Methods:** Medical records were reviewed from a cohort of 86 randomly selected persons with type 2 diabetes in an academic family medicine setting. Data were abstracted to assess the attainment of and change in five treatment goals related to glycemic, blood pressure, and lipid control from 1999-2003. Descriptive statistics were applied to demographic variables. Mean differences in outcomes were assessed with the paired t-test. The McNemar test was used to assess non-parametric variables, and the Wilcoxon signed ranks test was applied to differences achieved in mean goal scores for outcome variables.

**Results:** The mean numbers of treatment goals attained were 2.76 (SD = 0.92) in 1999 and 2.48 (SD = 1.1) in 2003. Significant improvements were noted in the mean values of HbA1c (0.4% decrease,  $p = 0.03$ ), diastolic blood pressure (4.3mmHg decrease,  $p < 0.001$ ), low-density lipoprotein cholesterol (LDL-C; 10.6 mg/dL decrease,  $p < 0.01$ ), and high-density lipoprotein cholesterol (HDL-C; 8.3 mg/dL increase,  $p < 0.001$ ) over the four-year study interval. No significant differences were noted in the percent at goal during the study for HDL-C or for HbA1c. A significant decrease was found in the percent at goal from 1999-2003 for LDL-C (from 79% to 40%, respectively). The decrease in the percent LDL-C at goal was explained by the more stringent practice guideline goals introduced in 2001 for diabetes (i.e., LDL-C < 100 mg/dL).

**Conclusion:** Despite significant improvement in mean values of modifiable risk factors, the percent of patients meeting 2003 guideline goals for HbA1c, systolic blood pressure, and LDL cholesterol did not improve. These findings suggest that patient-level improvements may not be adequate indicators of a practice's achievement of guideline recommendations. Percent attainment of guideline goals may be a useful performance measure of practice-level quality improvement initiatives.

**Key words:** Type 2 diabetes, blood pressure, HbA1c, hyperlipidemia, dyslipidemia, National Cholesterol Education Program (NCEP) Adult Treatment Panel guidelines, LDL cholesterol, body mass index, American Diabetes Association (ADA) Standards of Care, Primary Care

## Introduction

Diabetes has been diagnosed in approximately 13 million people in the United States, with an additional estimated 5.2 million cases remaining undiagnosed.<sup>1</sup> Cardiovascular disease (CVD) is responsible for approximately 65% of diabetes-related deaths, with a two- to four-fold higher CVD death rate noted among adults with diabetes versus those without diabetes.<sup>1</sup> As

such, the prevention of CVD is a primary goal in the management of patients with diabetes.

The American Diabetes Association (ADA) has put forth guidelines annually for several of the modifiable risk factors of CVD, including control of glycemia, blood pressure, and blood lipid concentrations.<sup>2</sup> The National Heart, Lung, and Blood Institute (NHLBI) has established widely used clinical guidelines for the screening and treatment of blood lipids [National

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Julienne K. Kirk, PharmD, CDE, BCPS, is Associate Professor in the Department of Family and Community Medicine, Wake Forest University School of Medicine. She can be reached at jkirk@wfubmc.edu or Medical Center Boulevard, Winston-Salem, NC 27157. Telephone: 336-716-9043.

Kenneth R. Huber, MS, is a medical student at Wake Forest University School of Medicine.

C. Randall Clinch, DO, MS, is an Assistant Professor in the Department of Family and Community Medicine.

Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults].<sup>3,4</sup> Consensus recommendations for blood pressure control have been established by the Joint National Committee (JNC) on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure.<sup>5,6</sup>

Many individuals with diabetes receive treatment in a primary care setting, and published literature indicates goals targeting CVD risk reduction among persons with type 2 diabetes are not being optimized.<sup>7-9</sup> The intent of the current study builds upon a previously published cross-sectional analysis,<sup>7</sup> which described the frequency with which ADA (hemoglobin A1c or HbA1c), NCEP (cholesterol), and JNC (blood pressure) goals were met in a family practice setting for persons with type 2 diabetes. Kirk et al,<sup>7</sup> revealed that overall blood pressure, low density lipoprotein cholesterol (LDL-C), and HbA1c values did not reach the goals for the guidelines in effect in 1999.<sup>3,5,10</sup> Evidence further demonstrating the benefits of achieving and maintaining blood pressure, LDL-C, and glycemic control has accrued since this initial publication.<sup>11-15</sup> Changes in the guidelines related to the control of blood lipids and blood pressure since our first study have led to recommendations for tighter control of these parameters (see Table 1).<sup>2,4,6</sup> The purpose of the current study was to conduct a follow-up analysis on the cohort of persons with diabetes from our previous study, focusing on the attainment of CVD-related guideline parameters (i.e., HbA1c, LDL-C, HDL-C, and blood pressure).

physician assistants, two registered nutritionists, and one pharmacist diabetes educator. Resident physicians, physician assistants, and faculty physicians care for patients seen in this practice.

The methods of this prior study are reported elsewhere.<sup>7</sup> Briefly, medical records were randomly selected using ICD-9 codes for type 2 diabetes and hyperlipidemia. Demographic variables (i.e., patient age, gender, and race) as well as height, weight, personal and family coronary heart disease history, tobacco use, total cholesterol, LDL-C, HDL-C, triglycerides, HbA1c, and systolic and diastolic blood pressure values were abstracted from a structured review of the medical record. The study protocol was approved by the Institutional Review Board. For the current study, follow-up data were available on 86 patients. Seven of the original 124 patients were excluded because they were involved in a clinical trial where management of blood pressure, lipids, or HbA1c was dictated by a study protocol, and 31 of the original patients were lost to follow-up (i.e., patient changed healthcare provider or died).

Descriptive statistics were performed to compute means, standard deviations, frequencies, and percentages for the demographic variables and for the lipid, blood pressure, body mass index, and HbA1c variables. Simple means were calculated for the lipid, blood pressure, and HbA1c variables. Chart data were eligible for abstraction if an office visit was associated with the collection of laboratory data. No patient had more than four eligible office visits for either year studied; missing values were

excluded from the analysis. The mean values for the lipid, blood pressure, and HbA1c values were then combined with the appropriate demographic variables to determine if a patient was meeting the goals recommended by the ADA or the NHLBI. The paired samples t-test was used to assess for a difference at the level of the patient in the means of the LDL-C, HDL-C, body mass index, HbA1c, and systolic and diastolic blood pressure values between the two study periods of 1999 and 2003 (two-sided alpha = 0.05). The non-parametric McNemar test was used to assess for a significant difference in the number of patients at

the identified goal for LDL-C, HDL-C, HbA1c, and systolic and diastolic blood pressure values between 1999 and 2003 (alpha = 0.05). A "goal score" was computed for each year, 1999 and 2003, with a value of "5" representing a person who attained the recommended goal for each of the five variables under study (i.e., for LDL-C, HDL-C, HbA1c, and systolic and diastolic blood pressure) for that year; a value of "0" represented a patient who met none of the goals for the five variables under study for that year. A histogram was created to depict the distribution of the goal scores for the years 1999 and 2003. The Wilcoxon signed ranks test was used to test for a difference between the mean "goal scores" as well as between the five individual variables from 1999

**Table 1.**  
**Guidelines for Persons with Diabetes**

Parameter	Year	
	1999	2003
HbA1c*	< 7%	< 7%
Systolic blood pressure†	< 130	< 130
Diastolic blood pressure†	< 85	< 80
LDL-C‡	< 160/< 130/< 100 mg/dL <sup>§</sup>	< 100 mg/dL
HDL-C‡	>/= 35 mg/dL	>/= 40 mg/dL

\* Based on American Diabetes Association guidelines

† Based on Joint National Committee for the Detection and Prevention of Hypertension Report, HDL-C = high density lipoprotein, LDL-C = low density lipoprotein

‡ Based on the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol

§ LDL-C goals based on risk stratification per NCEP Adult Treatment Panel (ATP) II<sup>3</sup>

## Methods

A cross-sectional analysis evaluating CVD risk factors and pharmacotherapy in a randomly selected sample of 124 persons with type 2 diabetes and hyperlipidemia was previously performed.<sup>7</sup> Data were obtained from an academic family medicine clinic in the southeast. Approximately 56,000 patient visits to this clinic are conducted annually, and the mix of insurance coverage includes Medicare (22%), Medicaid (12%), managed care (61%), and self-pay (5%). There are 30 medical residents in training along with three fellows, 15 faculty physicians, three

and 2003 (two-sided alpha = 0.05). All statistical analyses were carried out using SPSS (Version 12.0).

## Results

The mean age of our sample was 59.6 years (SD 12.6 years); 53.7% were women. Approximately 54% were African American, and 47% were white. Analyses of those patients from the baseline study lost to follow-up revealed no significant differences from those included in the current study, with the exception of higher mean total cholesterol and triglyceride measures (225 mg/dL versus 207 mg/dL,  $p = 0.03$ ; 357 mg/dL versus 217 mg/dL,  $p = 0.03$ , respectively).

There was an overall low percentage of missing data in the current study. The systolic and diastolic blood pressure variables had no missing data; the HbA1c and HDL-C variables had 1.2% missing data; and the LDL-C variables had 5.8% missing data. Missing data were excluded from analyses.

At the patient level, significant differences were noted at the 2003 follow-up for HbA1c (a 0.4% decrease;  $p = 0.03$ ), diastolic blood pressure (a 4.3 mmHg decrease;  $p < 0.001$ ), LDL-C (a 10.6 mg/dL decrease;  $p < 0.01$ ), and HDL-C (an 8.3 mg/dL increase;  $p < 0.001$ ). There was a trend toward a significant decrease in systolic blood pressure (a 3.5 mmHg decrease;  $p = 0.09$ ) (see Table 2). No difference was detected in the body mass index ( $p = 0.89$ ).

The number and percent of persons with diabetes "at goal" for HbA1c, systolic blood pressure, diastolic blood pressure, LDL-C, and HDL-C are listed in Table 3. While mean LDL-C improved by 10.6mg/dL between 1999 and 2003, the percentage of patients at goal for LDL-C significantly worsened (from 79.1% at goal in 1999 to 39.5% at goal in 2003;  $p < 0.001$ ). No significant differences were found among the other four variables, though there was a trend toward a significant improvement in the percent at goal for HDL-C ( $p = 0.09$ ).

Overall, mean goal scores were lower in 2003 than 1999 ( $p = 0.035$ ). The mean number of goals met in 1999 was 2.8 with a standard deviation (SD) of 0.92; only two patients met all five goals, while nine patients met only one goal (see Figure 1). In 2003, the mean number of goals met was 2.48 (SD 1.1).

Similarly, only two patients met all five goals; however, three patients did not meet any of the goals that year. When considering the five individual quality indicator variables of HbA1c, systolic blood pressure, diastolic blood pressure, LDL-C, and HDL-C, the only significant difference noted in goal scores was a decrease in the LDL-C score ( $p < 0.001$ ) from 1999-2003.

The 1999 NCEP ATP II LDL-C goals were then applied to our 2003 data. When applying these earlier criteria, no significant difference in the percentage of patients at goal for LDL-C was noted in the 2003 data: 83% (71/86) were at goal in 2003 vs. 79% (68/86) in 1999 (Chi-square 2-sided  $p = 0.19$ ).

**Table 2.**  
**Change in Quality Indicators 1999-2003**

Indicator	Mean (SD)	Mean (SD)	Difference	95% CI of the Difference
	1999	2003		(Lower, Upper)
HbA1c	8.6 (2.0)	8.2 (1.8)	-0.4	(-0.76, -0.05)
Systolic BP	137.6 (18.6)	134.1 (14.3)	-3.5	(-7.49, 0.55)
Diastolic BP	76.2 (9.3)	71.9 (9.2)	-4.3	(-6.38, -2.22)
LDL-C	125.5 (39.8)	114.9 (40.9)	-10.6	(-18.10, -3.09)
HDL-C	38.9 (11.2)	47.2 (12.1)	8.3	(8.55, 10.25)

SD (standard deviation), CI (Confidence Interval), BP (blood pressure), LDL-C (low-density lipoprotein cholesterol), HDL-C (high-density lipoprotein cholesterol)

**Table 3.**  
**Frequency "at Goal" for Quality Indicators 1999 vs. 2003**

Indicator	1999	2003 using 1999 standards	2003 using 2003 standards	Difference in number "at Goal"
	N (%)	N (%)	N (%)	
	At Goal	At Goal	At Goal	P value <sup>†</sup>
HbA1c	12 (14.1)	*	16 (18.8)	0.33
Systolic BP	32 (37.2)	*	34 (39.5)	0.86
Diastolic BP	72 (83.7)	79 (91.9)	68 (79.1)	< 0.001 <sup>‡</sup> 0.48 <sup>§</sup>
LDL-C	68 (79.1)	71 (82.6)	34 (39.5)	0.68 <sup>‡</sup> < 0.001 <sup>§</sup>
HDL-C	53 (61.6)	74 (86)	61 (71.8)	< 0.001 <sup>‡</sup> 0.09 <sup>§</sup>

\* No change in the 2003 standards occurred for this quality indicator, therefore the data are the same as those in the "2003 using 2003 standards" column,

<sup>†</sup> McNemar test

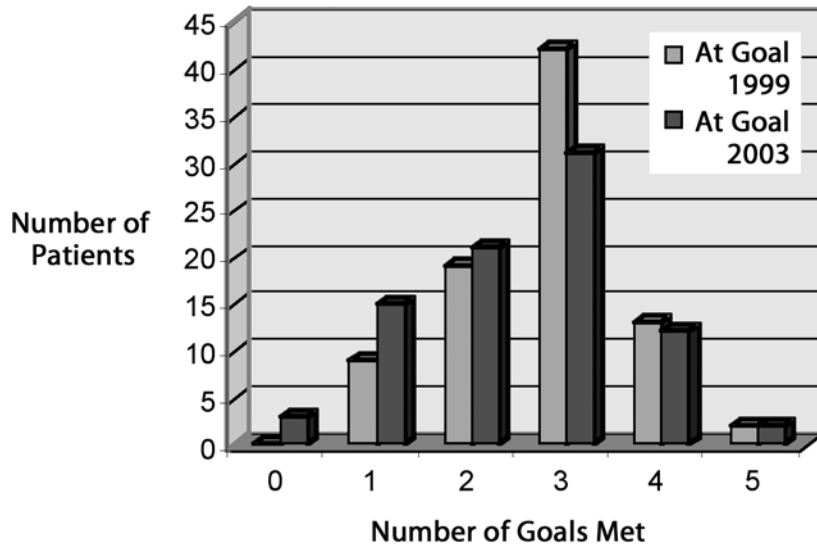
<sup>‡</sup> P value reflects the difference in number at goal for this quality indicator in "1999" vs. "2003 using 1999 standards"

<sup>§</sup> P value reflects the difference in number at goal for this quality indicator in "1999" vs. "2003 using 2003 standards"; BP (blood pressure), LDL-C (low-density lipoprotein cholesterol), HDL-C (high-density lipoprotein cholesterol)

## Discussion

While improvement with respect to decreased mean HbA1c, diastolic blood pressure, and LDL-C, and increases in the mean HDL-C were achieved over the four-year study interval, the overall number of patients at goal for LDL-C decreased by approximately 40% (see Tables 2 and 3). This paradoxical improvement in patients' mean LDL-C levels despite a decrease

**Figure 1.**  
**Number of Cardiovascular Disease-Related Guideline Goals Met (1999 vs. 2003)**



in the number of patients at goal for LDL-C in 2003, are explained by the change in the NCEP ATP III guideline with the introduction in 2001 of type 2 diabetes as a coronary artery disease equivalent and the new LDL-C goal of less than 100 mg/dL.

Attainment of goals targeting metabolic endpoints related to cardiovascular disease risk reduction among persons with type 2 diabetes has been studied among primary care providers.<sup>7-9</sup> Some primary care practices have used computer-assisted interventions to improve diabetes care with limited improvement in metabolic outcomes.<sup>16</sup> Compliance with blood pressure or lipid guidelines in cross-sectional data are based primarily on surrogate markers, such as reports of awareness of guideline recommendations,<sup>17</sup> physicians' perceived implementation of guidelines,<sup>18</sup> or performance of recommended screening tests.<sup>19</sup> However, even high rates of risk factor testing (HbA1c, blood pressure, LDL-C) have been shown not to correlate with optimal metabolic control among persons with diabetes.<sup>20</sup> Grant et al., found that high annual testing rates corresponded to only 34% of patients at goal for HbA1c (< 7%), 33% at blood pressure goal (< 130/80), and 46.1% at goal for LDL-C (< 100 mg/dl).<sup>20</sup> Primary care providers are not alone in their difficulty achieving practice guideline goals. Aliyu et al., reported that 38% of cardiologists' patients with established coronary heart disease and no contraindications to statin therapy had sub-optimal management of their dyslipidemia when compared against the NCEP ATP III guidelines.<sup>21</sup>

A previous cross-sectional study assessing ADA-specific lipid treatment goals among adults with type 2 diabetes in a university primary care setting revealed 42% were at goal for HDL-C, and 47% were at goal for LDL-C.<sup>8</sup> In a comparison of national samples of white, African-American, and Mexican-American persons with type 2 diabetes, Harris reported the percent of those with LDL-C values less than 100 mg/dL were

15.4%, 19.6%, and 21.1%, respectively.<sup>22</sup> The percent at goal for HbA1c (i.e., < 7%) for all subjects was 44.6%.<sup>23</sup> In the current study, we found that 71.8% (61/85) of patients were at goal for HDL-C in 2003, while only 39.5% (34/86) were at goal for LDL-C. Only 18.8% (16/85) were at goal for HbA1c (see Table 3). Most patients were at goal for only two of the five variables under study in both 1999 and 2003 (see Figure 1).

A limitation of the current study is its small sample size. The fact that the study patients were from an academic family medicine practice also limits the external validity of the study. While the patients seen in this practice are representative of a mixed population, greater than half of the patients have a managed care

plan. Additionally, this follow-up study included only persons with type 2 diabetes and a coexisting diagnosis of hyperlipidemia. It is possible that the percentage of those at goal for HbA1c may differ among persons with type 2 diabetes without hyperlipidemia. Another consideration is the potential confounding effect of the aging of our cohort; treatment goals may be more difficult to achieve with advancing age.

## Summary

This longitudinal study, conducted among a sample of persons with type 2 diabetes in an academic family medicine setting, describes the attainment of goals related to metabolic control and CVD risk reduction. The current study highlights the impact that changes in guideline recommendations can have on a practice's achievement of metabolic goals despite improvements at the patient level. We found that patients achieved on average approximately half of the guideline-specific goals related to CVD risk reduction. These results echo those of other investigators in that practice guideline goals are difficult to attain in the primary care setting. Further research is needed to elucidate the barriers related to attaining guideline-specific goals for patients with diabetes in primary care, such as short, infrequent visits; lack of information technology support; and competing demands.<sup>24</sup> Our findings suggest that patient-level improvements may not be adequate indicators of a practice's achievement of guideline recommendations. Percent attainment of guideline goals may be a useful performance measure of practice-level quality improvement initiatives.

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