

# Improvement of LDL-C Laboratory Values Achieved by Participation in a Cardiac or Diabetes Disease Management Program

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## ABSTRACT

Poor lipid control is a risk factor for cardiovascular diseases and diabetes complications. Frequently, however, patients with these diseases do not achieve blood lipid levels recommended by current standards of care. A retrospective study of 67,244 members eligible for disease management (DM) was initiated to evaluate the ability of interventions to promote improvement in low-density lipoprotein cholesterol (LDL-C) laboratory values for people with cardiovascular diseases or diabetes. The baseline trend in improving LDL-C values in the absence of DM was established. A two-year period prior to the start of the DM intervention was examined to measure the mean percent change in LDL-C values that was occurring in the population. The mean percent change observed for this pre-intervention group was then compared to the change in LDL-C values observed during the DM study period. A significant reduction in elevated LDL-C values (*F*-test;  $p < 0.0001$ ) was observed for members who participated in the DM interventions, even when elevated LDL-C was defined as low as  $\geq 70$  mg/dL. Members with LDL-C values within threshold limits maintained these levels during the DM program. The significant reduction in elevated LDL-C values and maintenance of optimal values ( $< 100$  mg/dL) was observed over the course of 3 years of participation in a DM program. A subset of the population also was examined to assess the impact of telephonic intervention on reducing elevated LDL-C values. A significant relationship between receiving care calls and reduction in elevated LDL-C levels was observed; members who received calls achieved up to a 32.5% relative reduction in elevated LDL-C values compared to members who did not receive calls. In conclusion, these findings demonstrate the ability of DM interventions to assist a large, geographically diverse member population in reducing a clinical laboratory value. (Disease Management 2006;9:360–370)

## INTRODUCTION

**A**CHIEVING AND MAINTAINING an optimal low-density lipoprotein cholesterol (LDL-C) level is critical for the management of cardiac risk. An elevated cholesterol level is ac-

cepted as an independent risk factor capable of leading to major cardiovascular diseases including coronary heart disease (CHD) and cerebrovascular disease, and possibly causing premature death.<sup>1</sup> A LDL-C level above the established clinical threshold is a major cause of

CHD<sup>2</sup>; this is of great consequence as CHD is the primary cause of mortality for Americans. In the next 14 years, CHD is estimated to become the number one cause of death in the world.<sup>3,4</sup>

Chronic elevation in LDL-C level is associated with progression of cardiovascular diseases, which can lead to secondary cardiac events.<sup>5,6</sup> LDL-C elevation also is a major risk factor for the progression of other chronic illnesses, particularly diabetes complications.<sup>3,5</sup> Cardiovascular disease is a common comorbidity of diabetes and is the primary cause of mortality for patients with type 2 diabetes.<sup>7,8</sup> Diabetes is a cardiovascular risk factor for patients with CHD and contributes to higher rates of morbidity.<sup>9–11</sup> Therefore, management of lipids is crucial for improved disease control for cardiovascular conditions and diabetes.<sup>12</sup>

Despite the importance of lipid management, a large percentage of patients with cardiovascular disease and/or diabetes still have LDL-C blood concentrations far exceeding evidence-based standards.<sup>2,8,13–15</sup> Although adherence to existing standards is poor, there is growing evidence to support the movement toward adopting even more aggressive LDL-C value thresholds.<sup>16,17</sup> It has been proposed that the current optimal value of less than 100 mg/dL be replaced with a substantially lower threshold of less than 70 mg/dL for individuals with CHD.<sup>5,6,16,18,19</sup> This proposal results from observing a decline in CHD event rates when LDL levels are reduced to this lower limit.<sup>6</sup> Coupled with this observation is the establishment of a continuous, linear association between LDL-C value and CHD events, pointing to the optimal LDL-C blood concentration needed to minimize cardiac events.<sup>6</sup>

The critical goals of all disease management (DM) programs are to promote healthy behavior, such as monitoring and improving LDL-C laboratory values, and to support the patient-physician relationship leading to better adherence to standards of care. Strengths of DM interventions are the ability to identify patients with cardiovascular diseases or diabetes and to advocate for appropriate adherence to evidence-based guidelines for the reduction of associated risk factors, such as LDL-C. A previous study has demonstrated a link between

DM interventions, with particular focus on DM telephonic interventions, and improved adherence to LDL-C testing.<sup>20</sup> However, it has been unclear whether an increase in adherence to clinical testing (a process measure) is associated with improved clinical values.<sup>8</sup> The primary goal of this study was to assess the ability of specific cardiac and diabetes DM programs to help members attain appropriate clinical LDL values. The clinical success of these DM programs was measured in part by the reduction of elevated LDL-C levels, while simultaneously maintaining optimal values in patients with cardiovascular diseases or diabetes who already were meeting current thresholds. This study is the first to measure the impact of a DM intervention on LDL-C laboratory values.

## METHODS

### *Member identification*

A member is defined as an individual who participates in a Healthways DM program as part of the care provided by their health plan. An Oracle 9i member database was constructed of members identified as having diabetes or cardiac disease (ie, CHD or heart failure [HF]) by their administrative claims using DM identification algorithms. This Oracle database was then queried to identify members for this retrospective study. A total of 67,244 members were identified based on member eligibility criteria for a diabetes or cardiac (ie, CHD or HF) DM program, on the presence of an administrative claim for a LDL-C test performed during the pre-intervention or DM intervention study periods, and on reported laboratory values in each of the two periods comprising a comparison group (further described below).

### *Member characteristics*

Members were grouped together based on how long they had participated in DM programs, regardless of the calendar or contract year participation began. Therefore, while the study period spanned 1998–2005, each of the comparison groups were comprised of a mixture of members participating during different

calendar years. This minimized the potential influence of external factors, such as changes in standards of care or other medical trends, from biasing the observed changes in LDL-C values as a result of DM programs. Furthermore, the study population was comprised of members from multiple and geographically diverse health plans providing broader applicability than studies focused on one health plan population. Overall member characteristics were evaluated and included age, gender, and disease burden. Disease burden was estimated by a member's level of healthcare resource utilization using the Johns Hopkins ACG software package.<sup>21</sup> The utilization of healthcare resources was expressed as a resource utilization band (RUB) that ranges from 0 (no utilization) to 5 (highest utilization). A RUB score for each member is based on his or her healthcare utilization for the first 12-month period in each comparison group.

#### Study comparison groups

The mean percent change in LDL-C laboratory values observed from year-to-year was calculated by comparing 12-month periods (Fig. 1). The first 24 months prior to the DM intervention were divided into pre-baseline and baseline periods. Changes in LDL-C values over this 24-month period prior to the start of the DM intervention (the Control comparison) were evaluated to establish the pre-DM population trend toward improved LDL-C control. Next, to measure the impact of the DM program, the DM Year 1 comparison group was evaluated to assess the mean percent change in LDL-C values between the baseline period and

the first 12 months of the DM intervention (Year 1). A one-month gap was included between the end of the baseline period and the start of the DM program to prevent a test initiated in the pre-intervention period from being counted in the DM year. The remaining comparison groups were the DM Year 2 comparison group (Year 1 compared to Year 2) and the DM Year 3 comparison group (Year 2 compared to Year 3), which were assessed to measure the impact of continued participation in a DM program.

#### Calculation of LDL-C values mean percent change

LDL-C laboratory values were obtained from laboratory reports processed on a monthly basis and were recorded in the laboratory module of the PopulationWorks<sup>SM</sup> database system. To be included in the study, a member must have had a test performed in each of the 12-month study periods comprising a given comparison group (Fig. 1). The mean percent change in LDL-C values was calculated by comparing the last available LDL-C laboratory value in each of the 12-month comparison periods. For example, the mean percent change for the Control comparison was calculated by subtracting the last LDL-C value observed in the baseline period for a member (end point) from the last LDL-C value observed in the pre-baseline period for that same member (initial), and then dividing by the pre-baseline value (initial). This same process was repeated for the two periods comprising each of the remaining comparison groups (Fig. 1). If more than one LDL-C value was reported in a given month,

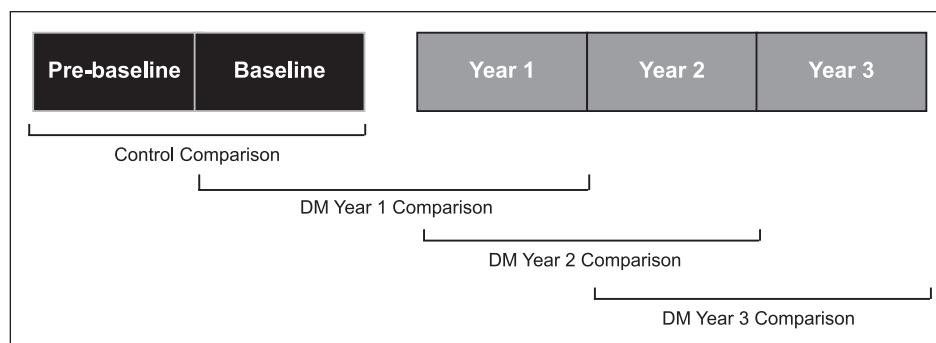


FIG. 1. Diagram of study comparison groups. Each box represents a 12-month period.

the lowest number was used for the initial LDL-C value and the highest number was used for the end point LDL-C value in the calculations. This was the more conservative approach because it may have underestimated the impact of the DM program. The absolute change in LDL-C values was calculated for each of the comparison periods as described above. The absolute change in LDL-C was reported as the difference between LDL-C values observed for the DM Year(s) compared to the Control comparison group.

#### *Analysis of comparison groups*

The mean percent change in LDL-C values obtained by the Control comparison group was compared to the change observed for each of the DM year comparison groups. The significance of the difference in LDL-C value change was measured using statistical techniques implemented via SAS software version 9.1.3. The general linear models (GLM) procedure was applied, the least square means were obtained, and the *p*-values were reported from the *F*-test estimating the significance of the treatment effect. Age and gender were included as covariates because both were identified as confounding variables.

#### *Analysis of comparison groups across several thresholds*

The ability to reduce elevated LDL-C values and to maintain LDL-C values within set limits was evaluated across several thresholds. An elevated LDL-C value was defined as 130, 100, or 70 mg/dL or greater than each. Similarly, maintenance of LDL-C values within the threshold of 130, 100, or 70 mg/dL or less was examined. The current, clinically optimal LDL-C, as defined by the American Heart Association, is less than 100 mg/dL, and this was the value targeted by these DM interventions. The DM clinician also would have considered the target level set by the member's physician (if known) and would have guided the member in taking action to achieve that target. The GLM procedure was applied as described above. Age and gender were included as covariates because both were identified as confounding variables. In addition, disease burden was a

confounding factor for the 70 mg/dL threshold only, but was included as a covariate for the entire threshold analysis to allow for unbiased comparisons across the thresholds.

#### *Analysis of shift comparison groups*

To better understand the magnitude of change observed in members' LDL-C values, a borderline category was examined in addition to the elevated and optimal thresholds. Member groups that had elevated LDL-C values (>110 mg/dL) in the pre-baseline period were evaluated in the baseline period to measure the shift in the percentage of members to borderline (100–110 mg/dL) or optimal levels (<100 mg/dL). Member groups that had borderline or optimal values in the pre-baseline period were similarly assessed. The shifts in the percentage of members in each category (elevated, borderline, or optimal) observed in the Control comparison were then compared to the shifts in LDL-C values observed in the DM Year 1 comparison group. The Mantel-Haenszel chi-square test was applied to measure the statistical significance of the shifts between categories for the Control comparison group versus the DM Year 1 comparison group, and the resulting *p*-values were reported. While the impact of age, gender, and disease burden could not be measured with this approach, these variables were adjusted for as a precaution by including them as covariates in the analyses.

#### *Telephonic intervention*

DM clinicians (ie, registered nurses, dietitians) call members during the DM intervention to guide them toward healthy behaviors. Based on the clinical status of members documented in the PopulationWorks system, DM clinicians educate members on current standards of care and, with the members, develop individual action plans that guide members in taking specific actions to improve their health and achieve certain outcomes. These calls include discussions about the importance of achieving and maintaining an LDL-C value of less than 100 mg/dL, and how to discuss with their physicians which LDL values are appropriate targets for them. If a member reported to a DM clinician that his or her physician had

set a particular target, the clinician would have assisted the member in obtaining this threshold.

In the final analysis, the relationship between the number of telephonic interventions a member received and the reduction in elevated LDL-C values ( $\geq 100$  mg/dL) was explored. The documented activity of telephone calls administered by DM clinicians (registered nurses) at Health/Care Support<sup>SM</sup> Centers during Year 1 of the DM intervention was assessed. Members were identified as receiving zero, one, two, three, or four calls, and the mean percent change in LDL-C values observed for these members was calculated by comparing the baseline period to the first year of DM (DM Year 1 comparison). The significance of the call effect was assessed using the GLM procedure, and the resulting *p*-value was stated. To measure the impact of receiving calls, the mean percent change obtained by called members was compared to the mean percent change obtained by members not called (primarily due to inaccurate phone numbers). This was reported as the relative reduction in elevated LDL-C values.

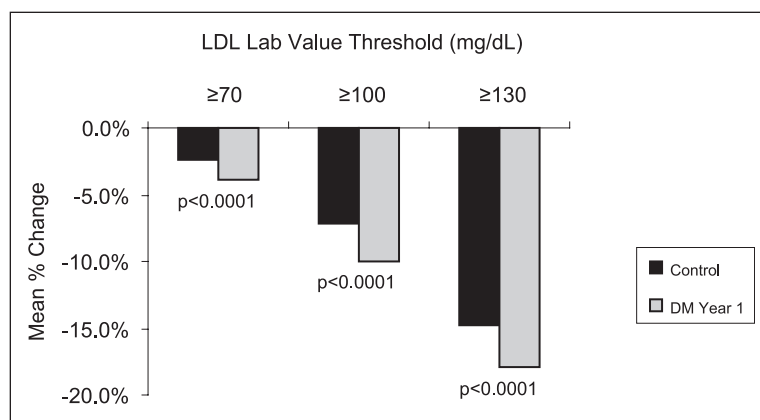
## RESULTS

The mean percent change in LDL-C values was evaluated in 67,244 members; the average age of this population was 59.7 and 44.4% were female. The average RUB score for these members was 3.5. Age, gender, and/or disease bur-

den were identified as significant confounding variables for many of the analyses performed and were adjusted to prevent these variables from biasing the results.

Evaluation of members with elevated LDL-C values (defined as 70, 100, or 130 mg/dL or greater) revealed a significant reduction in LDL-C values. Members enrolled in a diabetes or cardiac disease management program for one year (DM Year 1 comparison) significantly reduced their elevated LDL-C values (*F*-test for mean % change;  $p < 0.0001$ ) compared to the Control comparison group (Fig. 2). Members reduced their LDL-C values by 4.4 and 6.1 additional points, for the 100 and 130 mg/dL thresholds compared to the Control comparison group. These findings were robust even when elevated was defined by the most stringent conditions ( $\geq 70$  mg/dL), where a 2.5-point reduction was observed compared to the Control comparison group. In addition, members with LDL-C values within current optimal threshold limits ( $< 100$  mg/dL) maintained these optimal levels ( $-0.03$  mg/dL change) during the first year of intervention (DM Year 1 comparison group) compared to the Control comparison group (Fig. 3). Members also maintained LDL-C values below the 70 mg/dL threshold (2.8 mg/dL change) even though this threshold is below the current level targeted for adherence to standards of care (*F*-test for mean % change;  $p$ -value = 0.0681).

The remaining analyses measured the ability of the DM intervention to assist members in



**FIG. 2.** Reduction of elevated low-density lipoprotein cholesterol (LDL-C) values across several thresholds during participation in the disease management (DM) program.

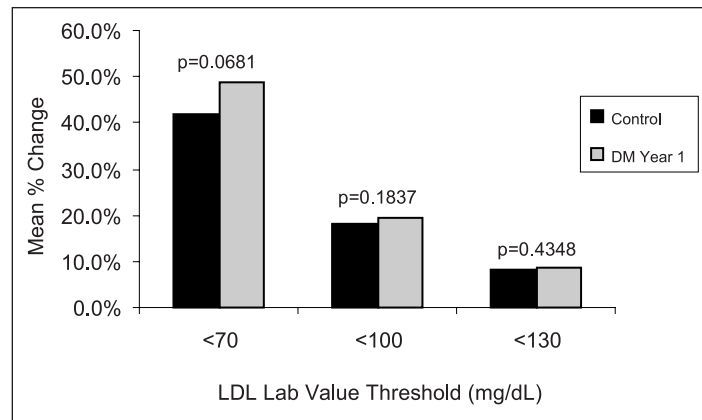


FIG. 3. Maintenance of low-density lipoprotein cholesterol (LDL-C) values within threshold limits (as defined) during participation in the disease management (DM) program.

achieving the current guideline of less than 100 mg/dL. The observation of the significant reduction of elevated LDL-C values after the first year of the DM intervention prompted further study of the magnitude of this reduction (few points versus non-trivial change). To accomplish this, a borderline category was introduced. Members who had elevated LDL-C achieved a significant shift (chi-square test;  $p < 0.0001$ ) toward optimal and borderline values during the first year of DM (DM Year 1 comparison group) compared to the Control comparison group (Table 1). This was observed as an increase in the percentage of members with optimal and borderline values coupled with a decrease in the percentage of members with elevated LDL-C values. Similarly, members who started with optimal or borderline values achieved a significant shift (chi-square test;  $p = 0.0073$  and  $p = 0.0008$ , respectively) toward optimal values during the first year of intervention (DM Year 1 comparison group) compared to the pre-intervention Control comparison

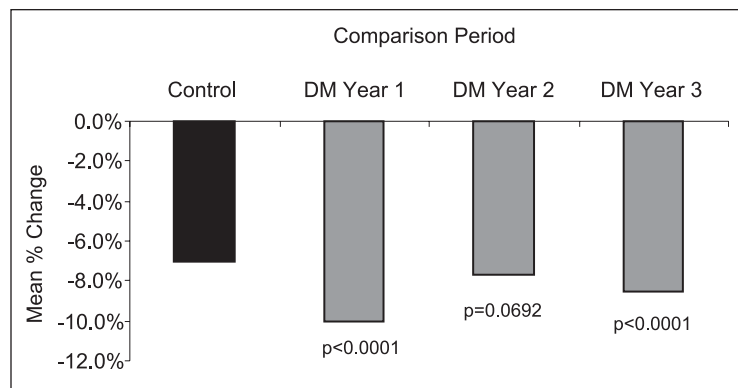
group. This was demonstrated by the increase in the percentage of members with optimal values coupled with the decrease in the percentage of members with borderline or elevated LDL-C values.

The ability of a DM program to help members sustain reductions in elevated LDL-C values and maintain their optimal LDL-C over several years was explored. The long-term reduction in elevated LDL-C values (defined as  $\geq 100$  mg/dL) was assessed by comparing the mean percent change in LDL-C values obtained by the Control comparison group to each of the DM Year groups (Fig. 4). For the analyses, the Control group was adjusted for age and gender relative to the particular DM year (Year 1, 2, or 3). As a result, each mean percent change value corresponded to a specific DM year comparison group. Because the Control comparison groups' mean percent change values were similar (ranging  $-7.0$  to  $-7.1$ ), the average value was represented (Fig. 4, black bar). As reported above, a statistically significant reduc-

TABLE 1. SHIFT ANALYSIS OF LDL-C VALUES IN CONTROL COMPARED TO DM YEAR 1

	<i>Optimal</i>			<i>Borderline</i>			<i>Elevated</i>		
	<i>Optimal</i>	<i>Borderline</i>	<i>Elevated</i>	<i>Optimal</i>	<i>Borderline</i>	<i>Elevated</i>	<i>Optimal</i>	<i>Borderline</i>	<i>Elevated</i>
Control	65.6%	13.9%	20.5%	36.4%	20.9%	42.7%	20.8%	12.2%	67.0%
DM Year 1 <sup>a</sup>	68.3%	12.9%	18.8%	42.1%	20.3%	37.6%	25.7%	12.7%	61.6%

<sup>a</sup>Statistically significant improvement during DM year 1 compared to Control ( $p$ -values  $< 0.01$ ).



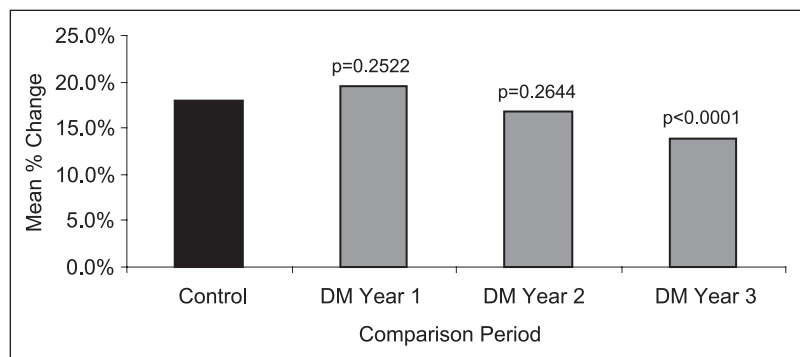
**FIG. 4.** Additional years of disease management (DM) sustains reductions in elevated low-density lipoprotein cholesterol (LDL-C) values.

tion in elevated LDL-C values was observed in Year 1 ( $-4.3$  mg/dL). Over the second DM year (Year 2), elevated LDL-C values were reduced ( $-0.6$  points), albeit not to a statistically significant level ( $F$ -test for mean % change;  $p = 0.0692$ ) compared to the Control comparison group. However, members achieved significant reduction of their elevated LDL-C levels ( $-1.4$  points) in DM Year 3 ( $F$ -test for mean % change;  $p < 0.0001$ ) compared to the Control comparison group.

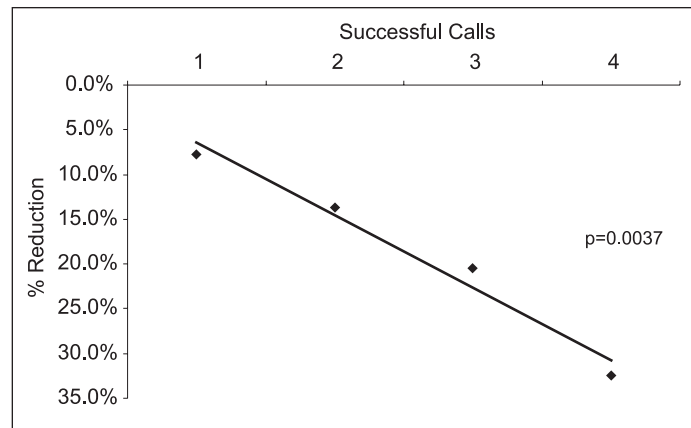
Members also were able to maintain optimal LDL-C values ( $<100$  mg/dL) while enrolled in the diabetes or cardiac program. The average mean percent change or fluctuation in LDL-C values in the Control comparison group (ranging from 17.7% to 18.3%) was compared to each of the DM Year groups (Fig. 5). In the first and second year of the DM program (Years 1 and 2), the optimal LDL-C values were sustained

compared to the Control comparison group ( $F$ -test for mean % change;  $p = 0.2522$  and  $p = 0.2644$ , respectively). However, members gained even greater control over their optimal LDL-C values in the third DM year, reducing already optimal values by 3.2 points ( $F$ -test for mean % change;  $p < 0.0001$ ), compared to the Control comparison group.

Lastly, the impact of telephonic intervention on reducing elevated ( $\geq 100$  mg/dL) LDL-C values was tested. The mean percent reduction in elevated LDL-C values obtained by members in the baseline period was compared to the reduction in values observed during the first year of DM intervention (DM Year 1 comparison group). The effect of calls on the reduction of elevated LDL-C values was significant ( $F$ -test for mean % change;  $p = 0.0037$ ), as indicated by the trend line (Fig. 6). In addition, a greater reduction was observed for members who re-



**FIG. 5.** Improvement in control over optimal low-density lipoprotein cholesterol (LDL-C) values during 3 years of the disease management (DM) program.



**FIG. 6.** Improvement in elevated low-density lipoprotein cholesterol (LDL-C) values after receiving calls during the first year of the disease management (DM) programs.

ceived more calls during the first year of DM intervention relative to members who were not called. For instance, members who received four calls achieved a 32.5% relative reduction in elevated LDL-C values compared to members who were not called ( $-4.6$  points).

## DISCUSSION

Members were evaluated for improvement in their LDL-C values during participation in Healthways DM programs. Two key features of this study design were important for minimizing the potential for selection bias to occur. First, members were grouped together based on their duration of participation in a DM program instead of grouping members by calendar year. Therefore, all comparison periods were comprised of a mixture of members enrolled during different calendar years, with more than 78% of members in each comparison period participating between 1999 and the second quarter of 2004 (prior to release of the 2004 National Cholesterol Education Program [NCEP] report). Secondly, this study calculated the change in LDL-C values over a 2-year period (Fig. 1). This design was especially important for estimating baseline trends in improving LDL-C values that occur even in the absence of disease management intervention. Furthermore, to prevent the calculated change in LDL-C values from being biased by differences in

member characteristics among the two periods, the same members continuously enrolled for the entire 2-year period were evaluated. This rigorous study design provides the ability to better estimate changes in LDL-C values attributable to participation in the DM programs.

Participation in these specific cardiac or diabetes programs promoted healthy behaviors and was associated with members' significant reduction of elevated LDL-C values and simultaneous maintenance of optimal values. In particular, the significant reduction of elevated LDL-C was achieved across multiple thresholds. Current American Heart Association guidelines recommend a LDL-C blood level of  $<130$  mg/dL for patients without risk factors and  $<100$  mg/dL for patients with known risk for cardiovascular disease or diabetes.<sup>22</sup> As such, existing cardiac and diabetes DM interventions target the less than 100 mg/dL value with their members as part of standards of care. However, emerging evidence-based medicine suggests that lower LDL-C serum levels are needed to prevent cardiac events.<sup>5,6,23</sup> While current DM interventions do not set 70 mg/dL as a goal, these DM programs are effectively achieving reduction of elevated LDL-C values to this lower limit by guidance from DM clinicians. This may also be the result of specific members' physicians setting this goal with them (possibly based on the 2004 NCEP report with the lower threshold),<sup>5</sup> and in turn, the DM

clinician may be guiding these members toward achieving this targeted LDL-C level.

The introduction of a borderline category helped evaluate shifts in the percentage of members with optimal or elevated LDL-C values. This borderline category was established to address the initial concern that shifts from elevated to optimal status may be the result of improvement achieved by members already near the threshold limit for optimal—for instance, a member who moved from 100 mg/dL (elevated) to 99 mg/dL (optimal). By including a borderline threshold (ranging from 100 to 110 mg/dL), it was possible to demonstrate that the significant reduction of an elevated LDL-C of greater than 110 mg/dL coupled with a statistically significant increase in the percentage of members with optimal values (less than 100 mg/dL) was due to a larger change in LDL-C blood levels. Given that there is a linear relationship between cardiac events and LDL-C values,<sup>24</sup> these findings demonstrate that these DM programs are assisting members to achieve a clinically meaningful reduction of elevated LDL-C values and assisting those members with optimal levels to maintain them.

Additional analyses revealed that DM interventions were not only able to promote improvement in LDL-C values, but also helped members maintain these improvements over the course of three years of participation in the program. The significant long-term reduction of elevated LDL-C values is critically important for appropriate lipid management in patients with cardiac disease or diabetes.<sup>5,25</sup> It also was observed that members with existing optimal levels maintained these values and gained even better control over their LDL-C levels in the third year of the program. Such findings emphasize the importance of continued participation in these DM programs to achieve and maintain improvement in clinical metrics.

Telephonic intervention was strongly associated with the reduction of members' elevated LDL-C values. A dose-dependent response was observed between the number of telephone calls a member received and the reduction in elevated LDL-C values. This finding was consistent with previous studies that have demonstrated a link between telephonic intervention and improved adherence to LDL-C

testing.<sup>20</sup> However, it has been unclear whether the increase in adherence to clinical testing (a process measure) is associated with improved clinical values.<sup>8</sup> The results from this study suggest that members are not only motivated to obtain clinical tests in association with DM interventions, but they are also improving actual clinical values during participation in these programs.

Evaluation of the member population revealed significant differences in age, gender, and/or disease burden. These variables were adjusted for in the statistical analyses employed to measure the significance of the DM programs. The observed impact of demographic characteristics on outcome measures emphasizes the need for continued vigilance in evaluating study populations for these known confounding variables. Identifying and controlling for such factors is essential to prevent these variables from biasing study results.

#### *Limitations and future studies*

*Study population.* Members were evaluated for improvement in their LDL-C values during participation in the DM programs. When monitoring changes in outcomes over time, there is the risk that external factors or medical trends may bias study results. The unique features of this study design minimized the potential for bias due to external factors, such as changes in standards of care and member characteristics. For instance, the NCEP report was released in August of 2004 and announced consideration of lower thresholds for LDL-C.<sup>5</sup> This report may have influenced these study findings. However, fewer than 21% of members in each of the comparison groups participated in the program during this time, and all comparison periods (Control and DM Years) contained members who participated during this time period.

This study calculated the change in LDL-C values over the two-year period for each of the comparison groups (Fig. 1). The same members continuously enrolled for the entire 2-year period were evaluated to prevent the calculated change in LDL-C values from being biased by differences in member characteristics among the two periods. However, this criterion lim-

ited the study population to only those members who had a test in both study periods, and excluded 32%–55% of members. The excluded members had laboratory values for only one of the two periods. Members included in the study who obtained regular testing (one test for each of the two periods) may be more prone to healthy behaviors compared to members with inconsistent testing patterns.

*Drivers of reduced LDL-C values.* Members significantly reduced their elevated LDL-C values during participation in the DM program. Future studies will further evaluate what elements of intervention may have contributed to this reduction. For example, the reduction in LDL-C value may be attributable to increased adherence to lipid-lowering medications. Similarly, there may be a relationship between goal setting by registered nurses to promote healthy behaviors (eg, diet, exercise) and systematic reduction of LDL-C values. The future evaluation of these types of processes may reveal specific actions driving the successful reduction of elevated LDL-C values observed during participation in these DM programs.

*Characteristics of comparison groups.* One component of this study examined the impact of telephonic intervention on reducing elevated LDL-C values. The reduction in LDL-C levels obtained by members who were called was compared to the LDL-C levels of members who were not called. Members comprising these two groups may have different characteristics, and these characteristics may impact the study results. For instance, the age, gender, and/or disease burden were identified as confounding variables and were accounted for to ensure an accurate comparison. However, there may be other unknown attributes that bias the responsiveness of members who are called compared to members who are not called. Future studies should continue to evaluate comparison groups for member characteristics that may influence outcome measures.

## CONCLUSION

In summary, this study demonstrates that these DM programs assist members in signifi-

cantly reducing a clinical metric and critical risk factor for cardiovascular disease and diabetes complications in accordance with current guidelines. Emerging medical research suggests that even lower LDL-C blood levels than those set by current standards of care may be needed to minimize disease risk. As a result, this study investigated the impact of DM on reducing LDL-C values to <70 mg/dL and clearly demonstrated that these current DM programs, in coordination with physician direction, are already encouraging such healthy behavior. Furthermore, members who remained participants in these DM programs obtained continued health benefits that will improve their disease control and quality of life.

## ACKNOWLEDGMENTS

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