# Evaluation of the *Know Your Health* Program for Type 2 Diabetes Mellitus and Hypertension in a Large Employer Group

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**Objective:** To evaluate the effect of an educational intervention program on clinical outcomes and on compliance with medical therapy in patients with type 2 diabetes mellitus (DM), hypertension, or both.

**Study Design:** Six-month randomized unblinded study.

**Methods:** Three hundred fifty-two patients were screened, and 347 were randomized to the intervention group (education through the *Know Your Health* [KYH] program [n = 174]) or to the control group (usual care [n = 173]). Evaluation of the effectiveness of the KYH program was based on the cohort of patients who were not at goal at baseline (124 in the intervention group and 115 in the control group). The primary research interests were to assess patient acceptance of the KYH materials and to compare the clinical outcomes of the intervention group with those of the control group.

**Results:** After 6 months, significantly more patients in the intervention group than in the control group were at goal (44.2% vs 29.2%, $P = .046$). Among patients with hypertension, reductions in the mean diastolic blood pressure were significantly greater in the intervention group compared with the control group at month 6 (–6.7 vs –3.6 mm Hg, $P = .04$). The groups did not differ significantly on other primary end points (percentage of patients with DM who were at goal, change from baseline glycosylated hemoglobin level, and change in Morisky score).

**Conclusions:** Participation in the KYH educational program during a 6-month period improved clinical outcomes in patients with type 2 DM or hypertension. The KYH materials were well received and were considered informative and easily comprehensible by patients who completed the program.

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Cardiovascular disease is the number one killer in the United States.[1] According to the American Heart Association,[1] cardiovascular disease is the underlying cause of death in more than 910 000 adults, representing 37% of all deaths. Type 2 diabetes mellitus (DM) and hypertension are well-established risk factors for cardiovascular disease. An estimated 20 million persons (9.6% of adults) have DM, and 65 million persons (32.3%) have hypertension.[1] Uncontrolled DM undermines employee productivity and increases the use of healthcare resources (eg, hospitalization and physician visits) for the management of associated amputations, blindness, kidney disease, and nerve damage.[2] The effect is compounded by restrictions on activities of daily living and by a high incidence of depression.[2] Compared with their peers without DM, adults with DM are more likely to earn less, be unemployed, have more absences from work, and be limited in the type and amount of work they can perform.[2] By increasing the incidences of heart disease, DM, stroke, kidney disease, depression, and lung disease, uncontrolled hypertension also raises healthcare consumption and costs, limits work, and contributes to coronary heart disease, the leading cause of premature permanent disability in the United States.[3,4]

Despite medications to control both disorders, nonadherence to protracted therapy has long been recognized as a major barrier to the optimum care of chronic diseases like DM and hypertension.[5-7] Adherence rates of 50% to 75% of prescribed dosages may be typical.[7-11] Attempts to improve adherence have taken the form of patient education, written information, behavior modification, cash incentives, and directly observed therapy.[12-15] Because education remains a cornerstone of optimal therapy, nonadherence may reflect inadequate or inappropriate education. This failure cannot be attributed solely to the patients and may serve to remind healthcare professionals that patients must understand why, how, and when to follow therapeutic recommendations. This study was performed to determine the effect of an education program (*Know Your Health* [KYH]) on clinical outcomes and on compliance with medical therapy among patients with DM, hypertension, or both in a large employer group.

## METHODS

### Study Plan

This 6-month randomized unblinded trial enrolled 300 patients whose type 2 DM or hypertension was uncontrolled according to criteria of the *Sixth Report of the Joint National Committee on Prevention, Detection*,

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*Evaluation, and Treatment of High Blood Pressure* (blood pressure, <140/90 mm Hg)[16] and the American Diabetes Association (glycosylated hemoglobin [A1C] level, <7.0%).[17] Screening sessions took place at Lockheed Martin's Georgia and Mississippi sites to identify the targeted patient population. All patients had a diagnosis, were in treatment with primary care physicians, and were being followed up through Lockheed Martin's tertiary prevention program, which assists with treatment compliance. Before randomization, those patients who were not at goal had baseline evaluations performed by the study team regarding blood pressure, A1C level, or both to determine if they still met the inclusion criteria. A randomization sequence was computer generated for each patient; once study eligibility was determined, patients received the next available randomization number. Approximately 150 patients each were to be randomized to the intervention group and to the control group. Eligible patients received an educational intervention (intervention group) or usual care (control group) during 6 months of follow-up. No medications were provided, and all participants in both groups were encouraged to see their physicians on enrollment. At the 3-month and 6-month follow-up visits, blood pressure readings and A1C levels were recorded by the study team. Before patient enrollment, the protocol was reviewed and approved by the Western Institutional Review Board, Olympia, Washington. Written informed consent was obtained before the screening procedures were completed.

Eligible patients were at least 18 years old with an established diagnosis of type 2 DM, hypertension, or both. Diabetes mellitus was defined as a random plasma glucose level of 200 mg/dL or higher (<11.1 mmol/L) with clinical symptoms, a fasting plasma glucose level of 126 mg/dL or higher (<7.0 mmol/L), or an A1C level greater than 7.0%. Hypertension was defined as a systolic blood pressure of 140 mm Hg or higher or a diastolic blood pressure (DBP) of 90 mm Hg or higher. Patients were required to speak English, not be pregnant or lactating, and be cognitively aware without a diagnosis of dementia or organic brain syndrome. Failure to meet these criteria was reason for exclusion, as were refusal to participate and absence of baseline values. The effectiveness of the intervention was based on evaluations at baseline, at month 3, and at month 6.

### Intervention

The present study was modeled after the ongoing Florida Health Literacy Study, which is using the KYH program in a community health center. The KYH program integrates established culturally sensitive health education practices for self-management of type 2 DM and hypertension with communication strategies and techniques designed specifically for populations with low functional health literacy. The KYH program in the present study provided 1 hour of education for patients with hypertension and 3 hours of education for patients with DM and was conducted by trained facilitators on Lockheed Martin property. Participants were encouraged, but not required, to enroll in the on-site fitness center, and any and all physical activity was promoted. Individual programs were not monitored. The program also provided patients with diet and exercise regimens and with tools to track visits to their physicians.

### Statistical Analysis

The statistical analysis plan was finalized before database quality control and evaluability assessments were made and statistical analyses were conducted. The primary analysis cohort included all patients who were not at goal for hypertension, DM, or both at baseline and who had at least 1 postbaseline visit. Analyses were conducted at the month 3, month 6, and end point visits (end point was taken as the last postbaseline assessment for each patient). Secondary analyses were conducted on the subsets who had DM or hypertension. Participants with dual diagnoses were included in both subsets. Categorical measures, such as the number of patients at goal, were assessed using the general association variant of the Cochran-Mantel-Haenszel $\chi^2$ test. At each time point, analyses of covariance were applied to continuous measures, such as the changes from baseline in blood pressure. To provide additional statistical power, changes from baseline in A1C level and in systolic blood pressure and DBP at the 3-month and 6-month evaluations were analyzed using linear contrasts with repeated-measures random-effects models (PROC MIXED, SAS software version 8; SAS Institute, Cary, NC). Descriptive statistics were calculated for all primary and secondary measures at baseline, at 3 months, and at 6 months. All statistical tests were 2-sided, and significance was set at $P = .05$. Enrollment of approximately 150 patients with uncontrolled disease per group was designed to provide 80% power, with a type I error rate of .05, to detect a 16% between-group difference in the percentage of patients at goal. The calculation was based on an assumed 30% response rate in the control group (46% in the intervention group).

## RESULTS

### Study Groups

At baseline, 352 patients were screened for enrollment, and 347 were eligible for randomization. Of those

patients not at goal, 124 were assigned to the intervention group and 115 to the control group (the efficacy-evaluable cohorts). Three patients were not evaluated at any visits and were excluded from the analysis. The study groups were well matched for demographics, work environment, general health, and responses to baseline questions (**Table 1**). Most patients in both groups were white or African American men. Their age ranged from 22 to 80 years, and most participants had at least some college or technical school education. Almost all patients worked full-time on the first shift, with about 50% in manufacturing. Annual salaries averaged between $50 000 and $75 000. Approximately 90% of both groups described themselves as nonsmokers. Participants generally reported that they were recreational exercisers who rated their health as good and had no health-related limitations in carrying out moderate activities or in climbing stairs. The Short Test of Functional Health Literacy in Adults scores indicated a more than adequate literacy level in 98.6% of patients.

**Table 1.** Baseline Characteristics

| Characteristic | Intervention Group (n = 124) | Control Group (n = 115) |
|---|---|---|
| **Age, y** | | |
| Mean | 51.4 | 52.2 |
| Range | 28-80 | 22-79 |
| **Male sex** | 80.2 | 84.6 |
| **Race/ethnicity** | | |
| White | 61.0 | 62.9 |
| African American | 36.2 | 32.4 |
| Hispanic | 2.9 | 1.0 |
| Native American | 0.0 | 1.0 |
| Asian | 0.0 | 1.9 |
| Other | 0.0 | 1.0 |
| **Education** | | |
| Some high school | 1.9 | 1.0 |
| High school graduate or general equivalency diploma | 26.4 | 22.1 |
| Some college or technical school | 43.4 | 53.8 |
| College graduate | 16.0 | 9.6 |
| Graduate credits | 1.9 | 1.9 |
| Graduate degree | 10.4 | 11.5 |
| **Work environment or job description** | | |
| Engineering | 14.7 | 15.8 |
| Administrative | 16.7 | 16.8 |
| Manufacturing | 50.0 | 57.4 |
| Management | 18.6 | 9.9 |
| **General health (self-reported)** | | |
| Excellent | 1.9 | 1.0 |
| Very good | 22.6 | 22.1 |
| Good | 58.5 | 50.0 |
| Fair | 14.2 | 24.0 |
| Unknown | 2.8 | 2.9 |

Data are given as percentages unless otherwise indicated.

At baseline, 24 patients (6.9%) had DM only, 229 (66.0%) had hypertension only, and 91 (26.2%) had a dual diagnosis (**Figure 1**). Overall, 23.6% of the intervention group and 17.6% of the control group left the study prematurely, with 76.4% and 82.4%, respectively, completing the study. Between 92.9% and 100.0% of patients with DM tested their blood glucose level regularly (5-6 days/wk) (**Table 2**). Between 56.4% and 60.9% of patients with hypertension tested their blood pressure regularly (5-6 times/mo). More patients with DM (85.7%-95.2%) took medication than patients with hypertension (67.4%-69.1%). Substantially more patients with DM (57.1%-81.0%) reported having received education about their condition compared with patients with hypertension (13.0%-13.8%).

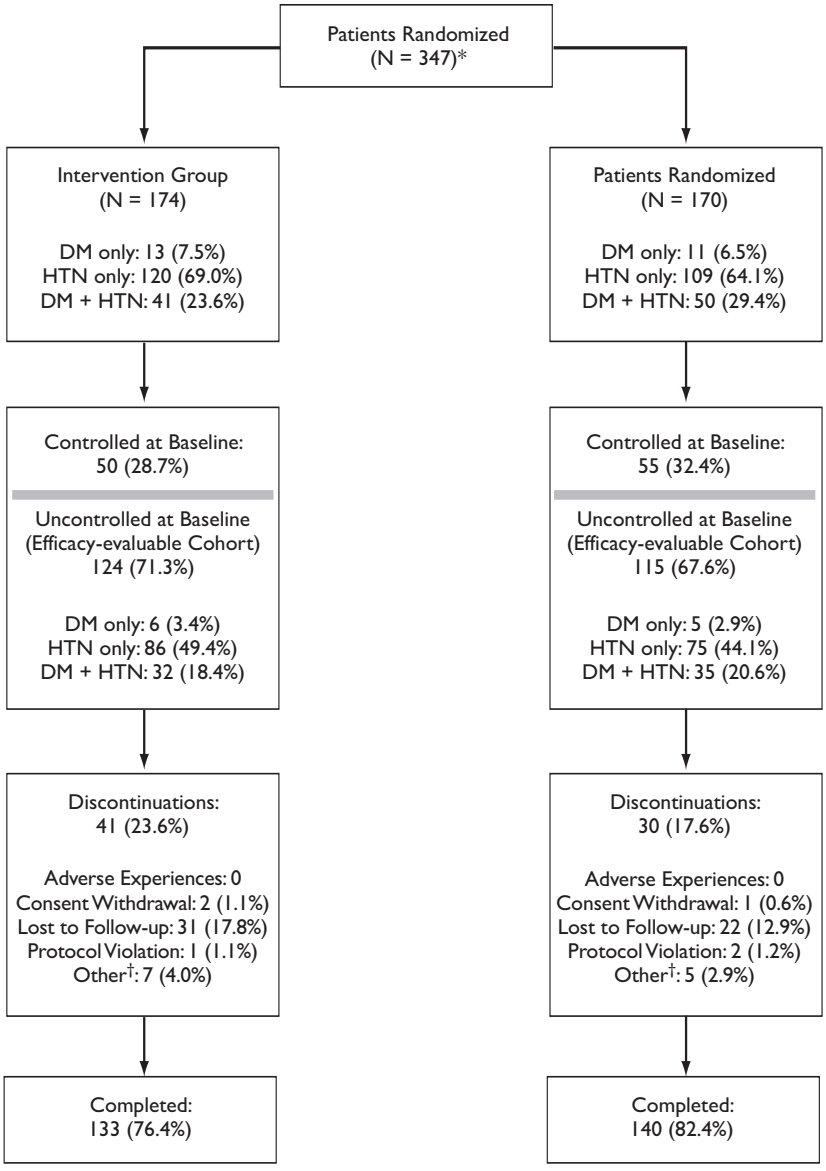
### Goal Achievement

After randomization to the intervention group, the percentage of patients in the efficacy-evaluable cohort who reached goal was 30.0% at month 3, with a further increase to 44.2% at month 6 (**Table 3** and **Figure 2**). The proportion of the control group that reached goal after randomization was greater at month 3 (33.3%), dropping to 29.2% at month 6. The difference in goal achievement between the groups was statistically significant in favor of the intervention at month 6 ($P$ = .046).

### Changes From Baseline in Glycosylated Hemoglobin Level (Patients With DM)

There were no statistically significant between-group differences for changes in A1C level from baseline to

**Figure 1.** Disposition of Patients*




*Three patients were not evaluated at any visits and were excluded from the analysis.
†Retired, no longer employed, transferred, or deceased.
DM indicates diabetes mellitus; HTN, hypertension.

month 3 or month 6 (Table 3). The repeated-measures analysis also showed no significant differences in this variable, primarily because of the small number of patients with DM enrolled.

### Changes From Baseline in Blood Pressure (Patients With Hypertension)

The mean systolic blood pressure and DBP decreased from baseline to the postbaseline evaluations in the intervention group and in the control group (Table 3). These decreases were consistently larger in the intervention group at month 3 and at month 6. The difference in DBP reduction at month 6 was significantly greater in the intervention group ($P = .04$) based on a repeated-measures analysis.

### Morisky Score

In both groups, mean Morisky scores indicated a shift toward higher-level compliance behavior at month 3 and month 6, although no statistically significant differences between the groups were seen (Table 3).

### Readiness to Change Questionnaire (DM Only)

The mean scores on the Readiness to Change Questionnaire increased relative to baseline in both groups at month 3 and month 6 (Table 3). The difference between the groups was not statistically significant.

### Patient Satisfaction Questionnaire (Intervention Group Only)

In the intervention group, 83.3% of patients with DM and 86.6% of patients with hypertension were very satisfied with the KYH intervention program. Most patients, including those with the highest levels of education, rated the program as 4 or 5 on a 5-point scale. Most patients also expressed appreciation that their company provided the program and indicated that they would attend similar learning programs covering other diseases.

### Changes in Additional Measures

The groups did not differ significantly in the change from baseline body mass index. By month 3 according to a questionnaire on patient characteris-

tics, 73.3% of the intervention group had seen their physicians since their last visit compared with 63.3% of the control group. This behavior allowed more intervention patients than control patients to change their regular medication (47.8% vs 31.1%, $P = .02$).

## DISCUSSION

Systematic intervention with a program that integrates established culturally sensitive health education practices for self-management can help improve clinical outcomes in patients with

**Table 2.** Hypertension and DM Management at Baseline*

| Characteristic | Intervention Group | Control Group |
|---|---|---|
| **Patients with hypertension** | **(n = 95)** | **(n = 95)** |
| Diagnosed by healthcare professional | 96.8 | 98.9 |
| Test blood pressure regularly (mean, 5-6 times/mo) | 60.9 | 56.4 |
| Taking antihypertensive medication | 67.4 | 69.1 |
| Received education about hypertension | 13.0 | 13.8 |
| **Patients with DM** | **(n = 21)** | **(n = 29)** |
| Diagnosed by healthcare professional | 100.0 | 96.6 |
| Test blood glucose level regularly (mean, 5-6 days/wk) | 100.0 | 92.9 |
| Taking diabetes medication | 95.2 | 85.7 |
| Received education about DM | 81.0 | 57.1 |

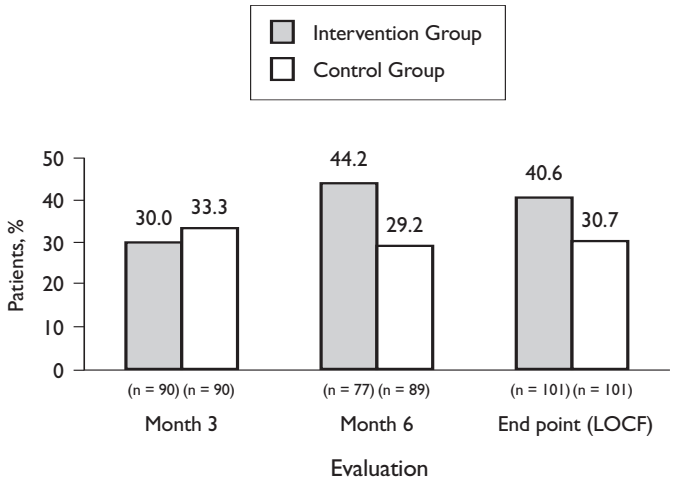
DM indicates diabetes mellitus.
*Data are given as percentages. One patient died during the study period, some were laid off, some retired, and 2 were transferred out of state.

**Table 3.** Primary and Secondary Efficacy Results

| Result | Baseline | Month 3 | Month 6 |
|---|---|---|---|
| ***Primary Efficacy Measures*** | | | |
| **Patients at goal, %** | | | |
| Intervention group | — | 30.0 | 44.2* |
| Control group | — | 33.3 | 29.2 |
| **Change from baseline glycosylated hemoglobin level, mean ± SE %** | | | |
| Intervention group | 8.9 | –0.6 ± 0.4 | –0.7 ± 0.4 |
| Control group | 9.0 | –0.5 ± 0.3 | –1.1 ± 0.3 |
| **Change from baseline systolic blood pressure, mean ± SE mm Hg** | | | |
| Intervention group | 152.2 | –7.6 ± 1.8 | –10.2 ± 2.0 |
| Control group | 151.9 | –10.3 ± 1.6 | –8.5 ± 1.8 |
| **Change from baseline diastolic blood pressure, mean ± SE mm Hg** | | | |
| Intervention group | 89.7 | –3.6 ± 1.1 | –6.7 ± 1.2† |
| Control group | 92.3 | –2.5 ± 1.0 | –3.6 ± 1.1 |
| **Morisky score (scale 0-4), mean ± SE** | | | |
| Intervention group | — | 3.4 ± 0.1 | 3.2 ± 0.1 |
| Control group | — | 3.3 ± 0.1 | 3.2 ± 0.1 |
| ***Secondary Efficacy Measure*** | | | |
| **Readiness to change score (scale 0-4), mean ± SE** | | | |
| Intervention group | 2.4 | 2.6 ± 0.2 | 2.7 ± 0.1 |
| Control group | 2.5 | 2.6 ± 0.2 | 2.9 ± 0.1 |

*$P = .046$ vs control group.
†$P = .04$ vs control group.
SE indicaes standard error.

**Figure 2.** Percentage of Patients With Uncontrolled Disease (HTN, DM, or Both) at Baseline Who Reached Goal During the Study




HTN indicates hypertension; DM, diabetes mellitus; LOCF, last observation carried forward.

type 2 DM and hypertension. In this study, statistically significant differences in the primary end points were observed after implementation of the KYH program. Significantly more patients in the intervention group were at goal after 6 months compared with the patients in the control group (44.2% vs 29.2%, $P = .046$). Although the mean blood pressure decreased in both groups, the intervention group demonstrated a significantly greater mean reduction in DBP compared with the control group at month 6 (–6.7 vs –3.6 mm Hg, $P = .04$). No statistically significant between-group differences were observed on other primary end points (percentage of patients with DM who were at goal, change from baseline A1C level, and change in Morisky score).

The KYH program was well received by patients assigned to the intervention group: 76.4% attended the educational session and more than 80% reported being satisfied with the program, indicating acceptance of the program and its benefits. This comprehensive program was designed to help patients with DM and hypertension take better care of themselves by educating them about their medical condition, the importance of a healthful diet and exercise, the need to check blood glucose level and blood pressure regularly and frequently, and the benefits of discussing these issues with their physicians. At the conclusion of the program, almost all participants felt healthier and in better control of their health. Even highly educated participants accepted the comparatively low educational level of the program materials.

The substantial blood pressure reductions in the intervention group likely reflect the effect of education and the reinforcement of adherence. The educational focus on understanding all relevant risk factors used a structured approach that emphasized the importance of lifestyle changes, follow-up with physicians, regular blood pressure monitoring, and adherence to study and nonstudy interventions, including medication use. The positive messages of the KYH program empower patients to reduce their risks by making feasible changes. The finding of substantial, albeit smaller, reductions in blood pressure in the control group suggests that enrollment in the study and increased interaction with healthcare professionals may have improved the adherence to treatment. Supporting this hypothesis is the fact that adherence in the control group improved as much as that in the intervention group, an effect observed in earlier clinical trials.[18-20]

The absence of effect on A1C level in patients with DM may have at least 2 explanations. First, the small number of these patients may have limited the statistical power to detect differences during follow-up. Second, the patients with DM in both study groups were at substantially higher levels of awareness and functioning about their disorder on entry than the patients with hypertension. For example, many more patients with DM had already been educated about their disease, were monitoring glucose levels regularly, and were taking appropriate medication. Patients with DM in the intervention group and in the control group may have already been taking better care of themselves and had less room for improvement.

In conclusion, the primary efficacy analysis of this study demonstrated that participation in the comprehensive KYH program significantly improved attainment of treatment goals, with a significant reduction in DBP in patients with hypertension. The KYH materials were well received and were considered informative and easily comprehensible by the study participants.

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