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CHIP Lifestyle Program at Vanderbilt University Demonstrates an Early ROI for a Diabetic Cohort in a Workplace Setting: A Case Study

Dexter Shurney, MD, MBA, MPH; Sandra Hyde, MSPS; Kristina Hulsey, MSPS

Summary
Several studies have found a strong dose-response relationship between most chronic diseases and lifestyle-related risk factors. This study examined the feasibility of a comprehensive, workplace-based, intensive lifestyle training program, to help type 2 diabetics alter the course of their disease within relatively short (6, 12 and 24-month) measurement windows. An additional purpose of this study was to determine whether health care cost savings could be achieved for the lifestyle group when compared to non-intervened type 2 diabetics within the same employer-sponsored health plan.
The Vanderbilt CHIP study measured participants’ pre- and post-intervention health care costs (total medical and prescription drug) and health services utilization on a year-over-year (Y0Y) basis, and compared them with the costs and utilization of the other (non-intervened) diabetics of the plan. Biometric and lab data were collected at the beginning and end of the program and six months after the study’s conclusion to document immediate and long-term changes in health outcomes and health risk behaviors.
Our six-month findings provide evidence that educating a member population about the benefits of a plant-based, whole-foods diet is feasible and can reduce associated health care costs.

Key Points
- Intensive lifestyle education and training is feasible in a workplace setting.
- Positive changes were seen among study participants in HBA1C and cholesterol results as well as positive changes in self-reported physical health and well-being.
- Health care costs were substantially reduced for study participants compared to the non-participant group.
- Approximately 23.8 percent of study participants have been able to eliminate one or more of their medications.

Introduction
CHRONIC ILLNESSES HAVE CONSISTENTLY been the largest determinant to rising health care expenditures in the United States and many other industrialized countries. A wealth of empirical evidence further suggests that 70 to 90 percent of such chronic illnesses as diabetes, cancer, cardiovascular disease, and stroke, and certainly death, from these common conditions are preventable and caused by poor lifestyle choices. In 2001, the Harvard Nurses’ Health Study concluded that 90 percent of type 2 diabetes was preventable and attributable to habits and behaviors not found in the low-risk pattern group. Moreover, studies have also found a strong dose-response relationship between most chronic diseases and lifestyle-related risk factors such as poor nutrition and sedentary living. Unfortunately, less than 2 percent of Americans meet all seven of the recommended Heart Health Goals: 1) Not smoking, 2) Being physically active, 3) Having a normal blood pressure, 4) Fasting blood-glucose levels below 100, 5) Total cholesterol levels below
200. 6) Maintaining a healthy BMI, and 7) Eating a healthy diet. 8

The United States National Institutes of Health recognizes lower cancer rates, lower risk of death from certain heart diseases, and lower LDL cholesterol levels in individuals with plant-based diets and regular physical activity. 9 An ongoing NIH study on the link between diet and disease is finding that the closer an individual's diet is to vegetarian, the lower his or her risk in the aforementioned health concerns. 9

The most frequently used lifestyle modifications include improvement in nutrition, tobacco cessation, and increased physical activity. Few studies have tested the overall effectiveness that comprehensive lifestyle programs may offer patients. However, those that have employed a more comprehensive approach have generally yielded positive results. Examples include:

PREMIER and DASH programs demonstrated reductions in obesity, blood pressure, and blood lipid levels, all of which are cardiovascular risk factors. 10

The Diabetes Prevention Program (DPP) found a higher percentage reduction in diabetes in the lifestyle intervention group over the metformin group. In the long-term analysis, "cumulative incidence of diabetes remained lowest in the lifestyle group." 11

ISAIAH in the UK, a "lifestyle-change intervention for pre-diabetic patients," observed a statistically significant difference between control and intervention groups in three markers for risk of progression to diabetes: weight, BMI, and waist circumference. 12

The Look AHEAD Trial, a four-year lifestyle intervention program, produced short-term improvements in glycemic control and CVD risk factors in individuals with type 2 diabetes, as well as long-term improvement in weight, fitness, HbA1c, SBP, and HDL-C. 13

The Prevention Plan "revealed that prevention programs based on the clinical practice of preventive medicine are able to achieve measurable health risk reduction in just one year." 14

In spite of the substantial evidence supporting the
Efficacy of comprehensive lifestyle programs to control, and at times reverse, many common chronic conditions, very few patients in usual primary care settings are offered the opportunity to participate in such programs.

Definition of Lifestyle Medicine
According to published statements by the American College of Lifestyle Medicine, “Lifestyle Medicine” is the use of lifestyle interventions in the treatment and management of disease. Such interventions include diet (nutrition), exercise, stress management, smoking cessation, and a variety of other non-drug modalities.

Definition of CHIP
The Complete Health Improvement project, (formerly known as the Coronary Health Improvement Project), CHIP, was founded by Dr. Hans Diehl and is a “lifestyle enrichment program designed to reduce disease risk factors through the adoption of better health habits and appropriate lifestyle modifications.” It serves as a reproducible model for lifestyle medicine as it demonstrates the point that chronic diseases can be turned around through responsible lifestyle changes. The Vanderbilt application of CHIP emphasizes a whole-food, plant-based diet.

Purpose
The purpose of the present case study was twofold. We sought to examine the feasibility of conducting a comprehensive, population-based, lifestyle program, such as CHIP (Complete Health Improvement Program) in our workplace setting. Additionally, we sought to measure its impact in helping individuals with a lifestyle-related chronic illness (in this case type 2 diabetes) alter the course of their disease and reduce their health care costs within defined six-12- and 24-month measurement windows. This report presents the outcome of short-term results at two and six months.

Background
The prevalence of diabetes has been increasing and rose from 6.5 percent in 1999 to 7.8 percent in 2006. With this rise in disease burden, health care
expenses are destined to escalate. It is projected that the percentage of national health care expenditure of people with type 2 diabetes mellitus (T2DM) will increase from 10 percent in 2011 to 15 percent in 2031.20

The Vanderbilt University and Medical Center Health Plan (VHP) in Nashville, Tennessee, averages 47,000 covered lives. The paid claims for T2DM are three-and-a-half times higher, per patient, than the claims costs for non-diabetic members. The annual VHP claims expense per T2DM has been increasing an average of 11 percent annually during the past four years.

Methods
Design Overview
The voluntary-participation study was free of charge and emphasized the participants’ roles in controlling health status through structured discussions / lectures, lifestyle and nutritional videos, and cooking demonstrations. The study measured participants’ pre- and post-intervention health care costs (total medical and prescription drug) and health services utilization on a year-over-year (YOY) basis, and it compared them
with the costs and utilization of the other (non-intervened) diabetics in the plan. In addition, biometric and lab data were collected at the beginning and end of the program as well as at six months after the study’s conclusion to document immediate and long-term changes in health risk behavior.

**Setting and Participants**

Although the CHIP model could be applied in a lay or community setting, we focus on its application in the workplace. This study presents an application of CHIP initiated by the VHP in conjunction with Vanderbilt’s Center for Integrative Health and The Dayani Center to Vanderbilt employees. Approximately 5 percent of VHP members have T2DM. During the past four years for which comprehensive claims data are available, an average of 400 VHP members are newly diagnosed with T2DM each year, and approximately 2 percent of the remaining VHP members have conditions that put them at risk for developing T2DM.

We chose T2DM for this study for a number of reasons beyond the inherent costs associated with this population. First, there is a strong relationship to lifestyle and T2DM which makes it an ideal condition to analyze with respect to the intervention. Finally,
it is a rather straightforward condition to identify and track within medical and pharmacy claims data. We chose the employee worksite as the location of this activity as a measure for evaluating the feasibility of program implementation within the workplace.

The study recruited adult employees of Vanderbilt University and/or Medical Center on a voluntary and first-to-enroll basis who responded to a general campus communication for the study. Eligibility requirements were clinical diagnoses of T2DM while having at least two consecutive years of coverage under the Plan. Additionally, participants were asked to commit to attend a minimum of 11 of 14 training sessions (80 percent).

There were, originally, 30 people in the pilot. Two withdrew prior to the conclusion of the CHIP program due to changes in employment status that resulted in the loss of VHP coverage. The age range of the pilot participants was 35 to 65, and the majority of participants were female. While the socioeconomic status of the participants was not recorded directly, the best estimable measure of this dimension comes from the salary-banding data tracked within the health claims database. The breakdown of the salary band data is shown in Exhibit 1.

**Intervention- Group sessions**

The primary intervention used in this study was CHIP, shortened from the usual three-month program duration to two months, during which participants met regularly in an onsite classroom setting for educational, instructional, and experiential health training sessions. During an eight-week period, Vanderbilt CHIP participants met for two-hour sessions twice weekly. To meet the needs of working families, meals were prepared for the participants by Vanderbilt Dining Services using recipes from *The Optimal Diet: The Official CHIP Cookbook*. Participants also received copies of the cookbook for use at home in their personal meal preparations. While eating healthy foods, participants watched program videos pertaining to lifestyle behaviors, which presented a variety of healthy learning objectives such as how to read food labels, and the importance of getting enough sleep, physical activity, and fiber on a daily basis. Participants were encouraged, as well as equipped, with practical "how-to" knowledge for incorporating healthy habits into their daily routines. Participants received instruction in whole-food, plant-based nutrition, exercise, and engaged in health discussions related to disease causation and the benefits of a healthy lifestyle as the basis of overall health and well-being.

It should be noted that although the study cohort was comprised entirely of type 2 diabetics, most of the education and training was not specific to diabetes education.

**Main Outcome Measures**

To determine if comprehensive changes to lifestyle for a cohort with a chronic-disease condition, in this case T2DM, could result in cost savings for an employer-sponsored health plan, prescription drug and medical claims cost data were collected and analyzed at pre-CHIP (Baseline, t = 0), post-CHIP (Baseline + eight weeks, t = 8), and CHIP follow-up (Baseline +26 weeks, t = 26). In order to provide a better level of understanding regarding changes in costs, biometric and lab data, were collected and documented at the same time intervals as claims data.

Copies of the biometric lab data were submitted by the participants for evaluation. These measures included body weight, HBA1C, LDL, HDL, total cholesterol, and triglycerides. It is noted, however, as the lab data submission was voluntary, for a total of eight participants, some element of the biometric data was missing at either the t = 0 or the t = 8 time frames. Well-being assessment data were collected at the same time intervals as claims data.

**Statistical Analysis**

To the extent possible, data for the total group was analyzed. Individuals who were lost to follow-up were excluded in the following well-being summary data but are still being followed in their health-claims data as long as they remain Vanderbilt employees. Numeric values have been rounded to the nearest whole number. P-values for statistical analyses were calculated on a two-sample, two-tailed t-test for unequal variances with the alternative hypothesis of \(\mu_1 \neq \mu_2\) (\(\alpha = 0.05\)).

The prescription drug and medical cost analyses were performed using actual VHP medical and prescription claims data. As claims data tend to be cyclical, identical time frames from 2010 were compared to the study period in 2011 for CHIP participants using all Non-CHIP members, as well as all Non-CHIP diabetics, as natural control groups.

To provide a basis to assess health status, and to corroborate the claims findings, laboratory and biometric data were collected. Changes in biometric data were evaluated at each of the three evaluation periods. Missing data were not imputed.

The Gallup-Healthways Well-Being Index® survey was administered at each of the three time frames (t = 0, +8, +26) and changes in scores between time frames 0 and +8, 0 and +26 were calculated to assess the participants' changes in well-being. The Well-Being Assessment included self-scoring in seven (continued on page 13)
analysis categories. The changes in survey scores for each participant were evaluated, and the average, between-member scores were calculated.

Results
At the six-month time frame, a total of eight participants were lost to follow-up. The data presented pertains to the 21 remaining participants (18 females and three males, ranging in age from 36 to 63 for the females and from 56 to 64 for the males).

Costs
A health care cost analysis was conducted on the accumulated VHP medical and prescription drug paid-claims data. The costs reflected in Exhibits 2 and 3 are average costs per member per quarter for all CHIP participants still employed and covered by the VHP, non–CHIP diabetic VHP members, and all non–CHIP VHP members in the same age range as the CHIP participants. The “All non–CHIP members” category includes all non–CHIP diabetics. Since VHP-paid claims can vary based upon the amount of copays that must be met, the data for copays has been included. Medical–claims costs include both in–patient (IP) and out–patient (OP) utilization as well as CP medications. Prescription drug claims (Rx) represent all self–administered prescription drugs obtained either through retail pharmacies or through a mail–order service. Exhibit 2 provides a presentation of the aggregate costs (medical and pharmaceutical) for all the participants in the study. For the CHIP participants, cost reductions occurred in both the first and second quarters following the program. Savings were realized year–over–year within the study group as well as when compared to non–CHIP diabetics and plan members as a whole.

Exhibit 3 provides a breakdown of the total claims costs in the categories of medical costs and pharmaceutical costs (Rx).

In an effort to understand where the cost reductions occurred, the utilization of services was measured in terms of OP medical visits (Exhibit 4), and prescription medications (Exhibit 5).

Utilization reduction in prescription medication was measured by evaluating the changes in the average number of prescriptions filled per patient as well as an attempt to evaluate where, by medication therapeutic classification, the changes occurred (Exhibits 5 and 6).

In Exhibit 6, the first column shows members that were identified during the second quarter that had ceased taking their medications for 90 days. The second column represents participating members who have accumulated a six–month period of time free from medications since the baseline period in the therapeutic classes indicated (Q1 represents a 90–day period that encompasses the baseline and eight–week time frames. Q2 represents a 90–day period that encompasses the 26–week time frame). At this point in time, approximately 23.8 percent of CHIP participants have been able to eliminate one or more of their medications since the start of the program intervention.

Laboratory Results
Changes in HBA1C, Total Cholesterol, LDL, HDL, and Triglyceride values were determined at t=0, t=8, and t=26. In Exhibits 7 and 8, with the exception of HDL, a positive number indicates a drop (or positive outcome) and a negative number indicates an increase in these values (or negative outcome). For HDL, since an increase is considered favorable, a reduction in this value indicates a negative outcome and an increased a positive outcome.

To determine if the changes could be sustained, the same lab parameters were measured six months after the start of the program. Exhibit 7 presents the improvements that occurred among the study participants and the percentage making those improvements at the indicated time periods:

Well–Being
In order to measure the immediate and longer term effects that a comprehensive lifestyle program might have on well–being, a validated and complete well–being assessment (WBA) was administered at baseline, eight weeks, and 26 weeks. Survey evaluation and scoring was conducted by Healthways™ both at the group level and at individual levels. The WBA included self–scoring in the following categories utilizing the Gallup–Healthways Well–Being Index Assessment Survey®:

- Life Evaluation
- Physical Health
- Emotional Health
- Healthy Behaviors
- Work Environment
- Basic Access
- Overall Well–Being Index®

The average changes in each individual’s response were evaluated, comparing the results after eight and 26 weeks to baseline measures. (Exhibit 8)
engagement could be realized in a sizable portion of the study group around a lifestyle program that had as its main tenets exercise and a plant-based diet. These findings suggest that this may be less of an issue than originally believed. Nearly two-thirds (54 percent) of our participants were engaged in the program at a level to effect a change in their labs or biometric measures. Data depicting lab values at two-months and six-months after baseline and comprehensive well-being assessments further support this statement on engagement. It is believed that this greater than expected acceptance, hence engagement, was due, in part, to the fact that the plant-based aspect of the program was never presented as a hard sell.

As a part of the biometric analysis, weight loss for participants was evaluated from zero to six months. 54.17 percent of the members have lost an average of 9.4 pounds (median = 7 lbs). 37.5 percent of the members have gained an average of 13.7 pounds (median = 9.4 lbs).

The changes in lab values reflect the effect of eight weeks of intensive CHIP training on diabetic individuals. Significant change was observed in two measurements: Reduction in variation of the HBA1C values of the group (p=0.01) and reduction in mean LDL of the improvement group (p=0.01). This is noteworthy because reductions in HBA1C values are indicative of long-term blood glucose control, and reductions in LDL indicate dietary improvements that can lead to reductions in risk for coronary artery disease which is the number one killer among type 2 diabetics.

The same lab values were again assessed at 26 weeks following the baseline measurements. An improvement in the biometric lab results were seen in all areas except HBA1C at the 26-week mark. This suggests that ongoing group activity, or rigorous lifestyle coaching may be necessary in order to sustain the behavioral changes in lifestyle that were seen at the onset of the program. Weight loss, or gain, was not statistically significant. However, a slightly higher proportion of participants lost weight than gained weight.

The healthcare cost analysis, which compared identical time frames from 2010 to the CHIP study period in 2011 for all CHIP participants, all non-CHIP T2DM VHP members, and all non-CHIP members between the ages of 35 and 65, found savings across each comparison group. Total VHP-paid claims per member for the CHIP participants decreased against each comparative time frame, while the costs for the non-CHIP diabetics increased across both comparative time frames. The overall costs for all non-CHIP members decreased in the first quarter but increased in the second. Comparing Quarter one (Q1) of 2010 to Quarter one (Q1) of 2011, average copays per member decreased across all groups. However, the decrease for the CHIP participants was higher than the other two comparison groups. A slight decrease was noted for all CHIP participants and all non-CHIP members for the Quarter two comparisons. Again: this same time, the non-CHIP diabetics had higher out-of-pocket expenses.

Drug utilization changes were evaluated based on days' supply, product name (NDC), and therapeutic class. Our results showed favorable changes in prescription drug utilization: The length of time without possession of medication, in conjunction with discussions held with the participants, indicate that the gaps in possession were intentional and not due to participant negligence. However, it is too early to reliably know if the changes will be sustainable over a longer period of time. The data suggest that during the "engagement period," or shortly after the intervention, some members may be less likely to sustain the lifestyle habits that allow them to reduce or stop taking their medications. For that reason, the change we see over the time-interval covered in this six-month report will need to be followed and reassessed at the post-26-week time period. Nevertheless, the current findings seem quite promising with 23.4 percent of our study population able to eliminate one, or more, of their medications within a six-month period.

The therapeutic categories that demonstrated the most change in drug utilization were in the antidiabetic, anti-hyperlipidemia, cardiac, and gastrointestinal drug categories. As highly-processed, high-fat foods in the diet are replaced with high-nutrient and high-fiber foods, and as exercise is introduced into the lifestyle, it appears that individuals can rely less on insulin, cholesterol medications, and GERD-reducing agents to treat their conditions.

The bulk of the cost reduction changes came from lower utilization which resulted in lower medical expenses and drug costs (42.9 percent and 14.3 percent respectively, on average over both quarters). In total, the approximate healthcare cost (medical + prescription drug) savings for this six-month time frame was $99,582. Based on program costs of $32,000, the net savings of $67,582 represents a six-month return-on-investment (ROI) of roughly 2.1:1.

Comprehensive well-being assessments were conducted and scores were calculated by Healthways. The overall measure of well-being, via the WBA, improved over the baseline measure for both post-baseline time periods.

At the individual levels, work environment and
basic access scores decreased at the eight-week mark. However, the decreases were not statistically significant, and at the 26-week mark, the changes were positive compared to baseline. There was no change across the healthy behaviors category. All other categories reflected positive changes to the well-being scores at the eight-week mark, with statistically-significant changes occurring in the life evaluation scores, physical health, emotional health, and the overall Well-Being index. After 26 weeks, all categories, with the exception of healthy behaviors, had positive changes compared to the baseline well-being scores. Statistically-significant changes were noted at the 26-week mark in physical health and well-being index. The fact that responses for wellness in Healthy Behaviors decreased from the baseline to the 26-week mark may suggest that these participants have a better understanding of what healthy behaviors truly are, as a consequence of the educational training associated with the program. The statistically-significant changes in the Well-Being Index suggest that even small changes in lifestyle can improve one’s overall outlook on life.

**Conclusion**

The evidence that diet and exercise affect health and well-being is irrefutable. While findings are consistent with previous community-based research in this area, this study provides new evidence, from an employer perspective. This study demonstrates that educating a member population about the benefits of a plant-based, whole-foods diet is feasible, and can improve health outcomes and well-being for individuals suffering from a chronic condition like type 2 diabetes. The study was also intended to evaluate implementation and successful engagement among employees. Within alternative community settings, participants often receive peer support from family members and friends that can bolster engagement. There was uncertainty at the program onset surrounding the ability to actively engage employees in a work setting among workplace peers. Findings of this study suggest that it is possible to achieve engagement around changing lifestyle behaviors in an employee population in a workplace setting. And, that an intensive, comprehensive lifestyle program is capable of generating measurable savings with a meaningful return-on-investment (ROI) within a relatively short period of time.

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